AED 10™
Automatic External Defibrillator

User Manual

Software version 2.06.XX

WelchAllyn®

Advancing Frontline Care™

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Caution! Changes or modifications not expressly approved by Welch Allyn could void the purchaser's authority to operate the equipment.

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Preface

Important!

Read this Operators Manual carefully as it contains important information concerning your safety and the safety of others when using this Automated External Defibrillator. It is important that you are familiar with the operation and controls before operating the product.

Manufacturer	Welch Allyn Protocol, Inc.
Product Name	Welch Allyn AED 10 (and JumpStart)
Device Type	Automated External Defibrillator

Medical Device Registration

Welch Allyn and its distributors are required by FDA medical device tracking regulations and other national regulatory authorities to maintain records of end-users that purchase Welch Allyn's defibrillators. Please provide us with the information requested in the device registration card to assist us in complying with the defibrillator tracking requirement and to enable us to contact you promptly in the unlikely event that there is a problem with your defibrillator. If you transfer the defibrillator to another person or company please notify us of the new owner by calling Welch Allyn at 800-289-2500 (toll-free in USA) or 503-530-7500. Likewise, if the defibrillator is retired from use or otherwise permanently disposed of, please call and notify us and provide the date of retirement or disposition.

Manufacturer's Responsibility

Welch Allyn Protocol, Inc. is responsible for the safety, reliability, and performance of the Welch Allyn AED 10, only if the following conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by Welch Allyn Protocol, Inc.
- The Welch Allyn AED 10 equipment is used in accordance with the instructions for use.

User's Responsibility

The Welch Allyn AED 10 is intended for use by personnel who are authorized by a physician/medical director, and who have the following training and skills:

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- American Heart Association Heartsaver course, American Red Cross CPR/AED course, or equivalent.
- Training in the use of the Welch Allyn AED 10.

The user should be completely knowledgeable of the information in the Welch Allyn *AED 10 Users Manual*. Good judgment should be used when operating the Welch Allyn AED 10. To ensure patient safety and proper operation, use only Welch Allyn-authorized parts and accessories.

We recommend saving the AED 10 shipping container and packaging material for future use should your device require service or upgrades.

Contact and Technical Support

Please contact Welch Allyn (page ii) if you have any questions regarding this notice.

Indemnification Against Defects

Welch Allyn Automated External Defibrillators (AED 10)

US Customers

Welch Allyn Protocol, Inc. (Welch Allyn) provides the following indemnity to persons or legal entities that originally purchase or lease a Welch Allyn AED from Welch Allyn or an authorized distributor appointed by Welch Allyn (the Purchaser).

Welch Allyn will, at its cost, defend, indemnify, and hold harmless the Purchaser from third-party claims or legal actions for liability or damages resulting from bodily injury or death caused by a mechanical or electrical failure of the Purchaser's Welch Allyn-AED or the malfunction of the Purchaser's Welch Allyn-AED due to a defect in its design or manufacture.

This indemnity does not extend to or cover any claim or legal action for liability or damages in connection with the use of the Purchaser's Welch Allyn-AED to the extent caused by:

1. negligent operation of the Welch Allyn-AED, or failure to follow the sequential operating instructions for use of the Welch Allyn-AED, or
2. failures or malfunctions of the Welch Allyn-AED that are due to improper maintenance, including without limitation, malfunctions of pads or batteries that occur after expiration of their shelf life or malfunctions of repairs, replacement parts, pads, or batteries that are not provided by Welch Allyn.

This indemnification is expressly conditioned on the Purchaser's fulfilling the following obligations with respect to any claim for which indemnification will be requested (the Claim). The Purchaser will send to Welch Allyn, at the address shown below, written notice of the Claim, promptly after the Purchaser obtains knowledge of the Claim. The Purchaser also will provide to Welch Allyn all assistance reasonably requested by Welch Allyn for evaluation of the Claim or defense of the Claim. Such assistance will include:

1. providing to Welch Allyn possession of the Welch Allyn-AED involved in the Claim (including any electronic record created by the Welch Allyn-AED of the event involved in the Claim) for analysis of the cause of any failure, and

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2. providing to Welch Allyn and its counsel all other evidence relevant to the Claim, whether in the form of documents or testimony. Welch Allyn will promptly notify the Purchaser in writing if Welch Allyn determines that the Claim is not covered by this indemnity, and Welch Allyn shall have the unrestricted authority to defend or settle any Claims for which indemnification is required by this agreement. However, the Purchaser shall retain the right to participate, at its own expense, in the defense or settlement of any Claim that is covered by this indemnity.

Address for notification of Claims:

Welch Allyn Protocol, Inc.
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153

Attn: General Counsel

Phone: 315-685-2500
Fax: 315-685-4496

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1 Safety

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Conventions Used in the Manual

Warnings

Warnings alert the user to a special condition that could result in serious personal injury or death. In this manual, warnings are displayed as shown in the following example:

WARNING

Includes conditions, hazards, or unsafe practices that can result in serious personal injury or death.

Cautions

Cautions alert the user to a special condition that could result in minor personal injury or damage to the equipment. In this manual, cautions are displayed as shown in the following example:

Caution

Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the Welch Allyn AED 10, or loss of data.

Notes

Notes contain information that augments or clarifies an operating step. Notes do not normally contain actions. They follow the procedural steps to which they refer. In this manual, notes are displayed as shown in the following example:

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Note The default supervisor password is 1-2-3.

Voice Prompts

The Welch Allyn AED 10 provides audio instructions through the built-in speaker to provide operating instruction and assist the user during defibrillation. In this manual, voice prompts are displayed as shown in the following example:

"Low battery."

General Cautions and Notices

Damaged

If the device has been damaged in any way, refer the device to qualified service personnel for servicing.

Labels

Observe all CAUTION and WARNING labels on the equipment and accessories.

Performance

The Welch Allyn AED 10 may not meet performance specifications if stored, transported, or used outside the specified storage or operating environmental range limits.

Notices

U.S. Federal law restricts this device to be used by or on the order of a physician. If the battery pack is removed for any reason, the user must label the Welch Allyn AED 10 as "Out of service due to battery operation."

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Patient Safety

General

WARNING Accessory adapter required for use on pediatric patients.

The AED 10 is not to be used on patients less than 8 years old or under 25kg (55 lbs), unless it is equipped with the accessory AED 10 Pediatric Energy Reducer (Welch Allyn part number 002168).

WARNING Ferromagnetic Equipment

ECG electrodes and cables contain ferromagnetic materials. They must not be used in the presence of large magnetic fields created by magnetic resonance imaging (MRI) equipment. The large magnetic fields generated by an MRI device could move ferromagnetic equipment with an extremely violent force that could cause serious personal injury or death to persons between the equipment and the MRI device.

Caution Patient Physical Harm

Place the Welch Allyn AED 10 in a position where it cannot harm the patient should it fall. Do not use adjacent to or stacked with other equipment. Keep all cables and connectors away from the patient's neck.

Shock Hazard

WARNING Defibrillation current can cause injury.

Do not touch the patient during defibrillation. Do not touch equipment connected to or metal objects in contact with the patient during defibrillation. Disconnect other electrical equipment from the patient before defibrillating.

Burns

WARNING Properly place defibrillation pads.

Do not allow defibrillation pads to touch each other, or to touch other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause patient skin burns during defibrillation and may divert defibrillating current away from the heart.

Remove excessive body hair, which may cause skin burns or ineffective energy transfer. Do not use alcohol, iodine, or other skin preparations. These can dry the skin and may cause the AED 10 to function improperly or may cause skin burns.

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Electrical Energy

WARNING Welch Allyn AED 10 can deliver 360 joules of electrical energy.

Disconnect any medical electronic device that is not labeled "defibrillation protected" from the patient. If this electrical energy is not discharged properly, it could cause personal injury or death to the operator or bystander. During defibrillation, the operator and all other people must stand clear of the patient, bed, and all conductive surfaces in contact with the patient.

WARNING Properly place defibrillation pads.

Do not place electrodes near the generator of an internal pacemaker. Always apply electrodes to flat areas of skin. Avoid application over folds of skin such as those underneath the breast or on obese patients. Excessive hair, poor adhesion, or air under electrode may produce burns.

ECG Misinterpretation

WARNING Properly place defibrillation pads.

Improperly placed pads may produce incorrect analysis and an inappropriate shock or no shock decision advisory.

WARNING Do not move patient.

Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis. Follow all instructions in the Users Manual.

WARNING Cardiac pacemakers may affect rhythm analysis.

Patient pacemakers may reduce the sensitivity of the Welch Allyn AED 10 analysis and errors in detecting shockable rhythms.

WARNING Radio frequency (RF) interference

Do not operate the Welch Allyn AED 10 in conjunction with electrocautery or diathermy equipment. Any equipment that emits strong radio frequency signals can cause electrical interference and distort the ECG signal to cause inaccurate interpretation of rhythm.

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Defibrillator and Electrode Pads

Explosion

WARNING Explosion hazard

Possible explosion hazard if used in the presence of concentrated oxygen or flammable anesthetics.

Electrical Shock or Fire Hazard

WARNING No internal, operator-serviceable parts

Do not open unit, remove covers, or attempt to repair the Welch Allyn AED 10. All servicing must be performed by qualified personnel.

WARNING Improper use can cause injury.

The Welch Allyn AED 10 contains an automatic disarm of the stored energy. If the operator has not delivered the energy to a patient or a test load, an internal timer will disarm the stored energy. This stored electrical energy can potentially cause death or injury if discharged improperly. Follow all instructions in this users manual.

Caution Do not immerse or expose the Welch Allyn AED 10 to water or other liquids.

Do not use the defibrillator if unit has been immersed in liquid or if excessive condensation is visible on the device.

Caution Conductive parts should not contact other conductive parts including the earth.

Improper Device Performance

WARNING Properly use electrode pads.

Do not attempt to warm the electrodes with a heat source greater than 35° C (95° F). Do not immerse or clean electrodes with alcohol or solvents. Do not perform chest compressions (CPR) through electrodes. These actions may damage the electrode pads cause the AED 10 to function improperly.

WARNING Use only accessories approved by Welch Allyn.

Do not use defibrillation pads, batteries, and other accessories not approved by Welch Allyn. Use of unauthorized accessories may cause the device to operate improperly and provide false measurements. Follow all labeling instructions on the defibrillation pads and the battery.

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Caution Do not repeatedly charge and discharge the defibrillator in rapid succession.

If a need for repetitive testing arises, wait at least 1 minute for every third discharge to avoid damaging equipment.

Caution Improper maintenance can cause improper performance.

Follow instructions in the Users Manual.

Battery Care

Caution Use only Welch Allyn batteries.

Use only Welch Allyn Part No. 001852 non-rechargeable lithium battery. Use of any other battery can damage the Welch Allyn AED 10.

Caution Always verify remaining capacity of a non-rechargeable battery after use.

Check capacity and change if battery is low. See "Maintenance Schedule" on page 56.

Caution Replace the battery at 5 years.

Battery replacement at 5 years is recommended due to degradation of the battery chemistry.

Care and Storage

Caution Clean and maintain the Welch Allyn AED 10 according to instructions. See "Maintenance" on page 53.

Do not clean the Welch Allyn AED 10 with alcohol, ketone, or any flammable agent. Do not autoclave the Welch Allyn AED 10 or attempt to sterilize the Welch Allyn AED 10 or any of its accessories.

Electrodes

WARNING Follow manufacturer's instructions for use of defibrillation electrodes.

Improper use of defibrillation electrodes may cause the Welch Allyn AED 10 to function improperly or may cause skin burns. Do not use expired, dry electrodes. Do not reuse disposable electrodes. Only use Welch Allyn approved electrodes or electrode adapters.

Caution Properly store and use defibrillation pads.

Store electrodes in a cool, dry location (between 60° and 95°F or 15° and 35°C). Do not sterilize the pads, immerse, or clean the electrodes with alcohol or solvents.

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Safety Symbols

Graphical symbols, letter symbols, and signs listed below may be found on the Welch Allyn AED 10 and accessories. Note the use of these symbols for safe and proper use of the equipment. For a list of icons that display operating status information, see "System Status Indicator" on page 17.

	Consult accompanying documents		Earth (ground)
	Defibrillator protected, type BF patient connection		Negative input terminal
	Dangerous voltage		Positive input terminal
	Altitude limit		Non-ionizing electromagnetic radiation
	Fragile		Humidity limit
	Stacking limit by number		Temperature limits
	Keep away from rain		This way up
$LiMnO_2$	Lithium Manganese Dioxide battery		
	Separate batteries from other disposables for recycling		
	Recycle the defibrillator and battery separately from other disposables (www.welchallyn.com/weee)		
	This device has been tested and certified by the Canadian Standards Association International to comply with applicable U.S. and Canadian medical safety standards.		
	The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.		

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2 Introduction

This chapter provides an introduction to the Welch Allyn AED 10 system and presents an overview of the Welch Allyn AED 10 controls, indicators, displays, and prompts. It also provides instructions for getting the Welch Allyn AED 10 ready for use and preparing the unit for storage.

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Overview

The Welch Allyn AED 10 (automated external defibrillator) is a safe, easy-to-use defibrillation device. The unit is lightweight and mobile and can be used in situations where there could be several minutes before the arrival of advanced life support (ALS) personnel.

The Welch Allyn AED 10 recognizes ventricular fibrillation and other ventricular tachycardia and guides operators through the defibrillation process. When properly connected to a patient who is unconscious, not breathing, and unresponsive (without signs of circulation), the Welch Allyn AED 10 analyzes the patient's heart rhythm, provides text and audio instruction prompts, determines if a shockable situation exists, and, if appropriate, automatically arms the Shock button.

The Welch Allyn AED 10 delivers the defibrillation shock through two self-adhesive, pre-gelled, low-impedance electrode defibrillator pads. The pads, cable, and connector are sold as disposable kits.

Note Although this User Manual refers to only the AED 10 automated external defibrillator, the manual describes the operation of both the AED 10 and the JumpStart automated external defibrillators configured with the software indicated on the front of this manual.

Features

- Two-button operation
- Extensive voice and visual prompts for the operator
- Continuous event recording for reporting each use to a printer or computer
- Weekly self-test to ensure readiness
- Biphasic energy output
- Lock-out protection to prevent inadvertent defibrillation
- Continuous surveillance of battery level

Qualified Operators

The Welch Allyn AED 10 permits trained users to administer a brief electrical shock to patients experiencing fibrillation or sudden cardiac arrest (SCA).

A qualified operator is someone who has successfully completed a CPR AED training course (e.g., AHA Heartsaver course or equivalent course provided by an accredited organization).

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Getting the Welch Allyn AED 10 Ready

Carefully unpack and inspect all the Welch Allyn AED 10 system components and accessories. Install the battery. Verify that the self-test passes before putting the unit into service. The device will perform an automatic self test upon being turned on.

Unpacking and Inspecting

Visually inspect the carton for any signs of damage or mishandling (carton perforations, cuts, or dents; bent or collapsed corners; or broken carton seal). Remove the Welch Allyn AED 10 from the carton and inspect it carefully.

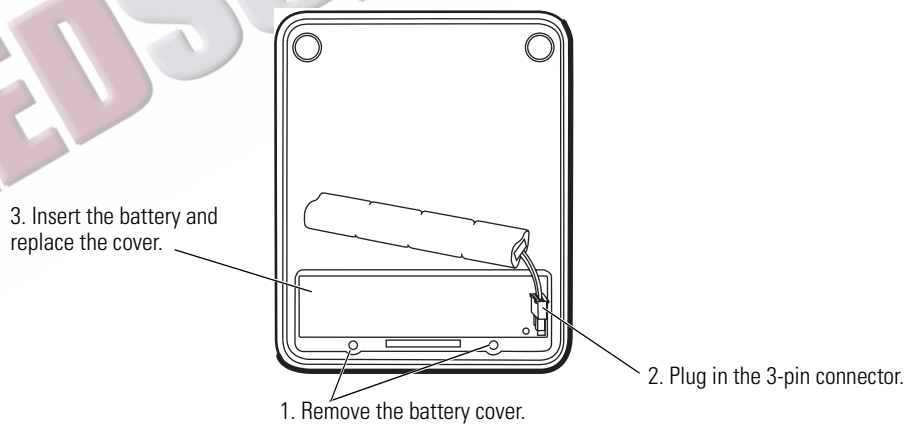
Before proceeding

1. Open and carefully unpack each carton.
2. Examine the instruments and accessories for signs of damage.
3. Check the packing list to determine that all accessories have been received.
4. Contact Welch Allyn (see page ii) if anything looks damaged or is missing.

Installing the Battery

The Welch Allyn AED 10 uses an extended-life, lithium manganese dioxide non-rechargeable battery.

To install the battery



1. Open the battery compartment (located near the bottom of the back of the AED 10) by removing the thumbscrews and then sliding the battery cover up and off.
2. Locate the 3 battery contact pins in the bottom-right corner of the battery compartment
3. Push the 3-pin battery connector onto the contact pins. The connector can be installed in either direction.
4. Place the battery into the battery compartment and replace the battery cover. Slide the cover back so that the screw holes are aligned.

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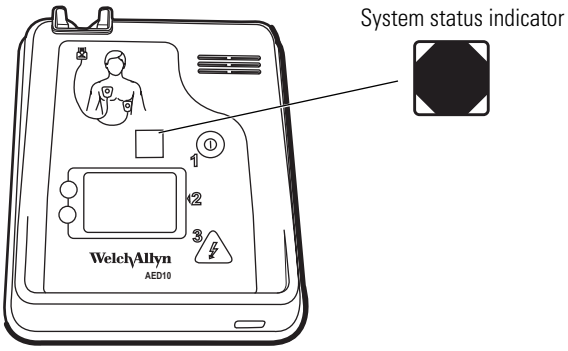
5. Replace the thumbscrews.
6. Cycle power by using the On/Off button.
7. Make sure the system status indicator (see page 17) in the center of the AED 10 indicates that the battery has sufficient charge. If the system status indicator displays anything other than the Battery Ready icon, the Welch Allyn AED 10 is not ready for use. See "Troubleshooting" on page 61.



Running a Self-Test

After installing the battery, the Welch Allyn AED 10 automatically powers up and performs a self-test. At power-up, the following tests are performed: battery, main processor, memory and program, stuck key, ECG acquisition system, and defibrillator.

Getting to Know the Welch Allyn AED 10

The Welch Allyn AED 10 is an automated external defibrillation (AED) device. It features a straightforward, three-step operating design that uses extensive voice and visual prompts to assist the operator. With continuous ECG and event recording, the Welch Allyn AED 10 maintains a detailed log that can be reported directly to a computer or printer.

Functions

This describes the following Welch Allyn AED 10 features:

- Controls
- Display
- Text Prompts
- Voice Prompts
- Icons
- System Status Indicator
- Infrared Data Port
- Event Documentation

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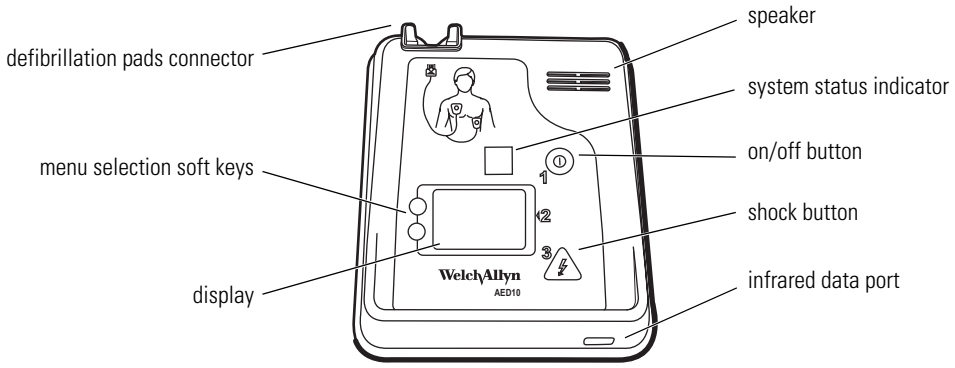
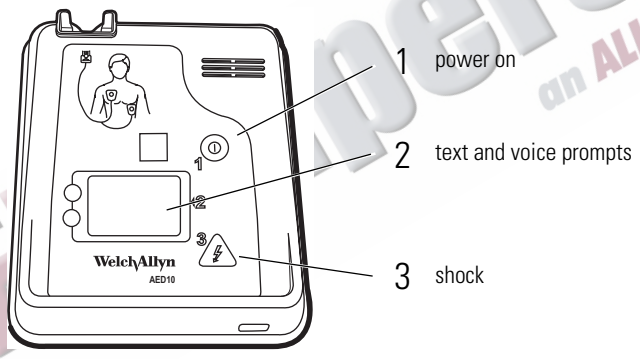


Controls

The Welch Allyn AED 10 is designed for ease of operation. After putting the defibrillator pads on the patient and connecting them to the Welch Allyn AED 10 unit, the operator performs this simple three-step process:

1. Turn the power ON.
2. Follow text and voice prompts.
3. If prompted, deliver shock by pressing the flashing red **Shock** button.



Power ON/OFF	Green ON/OFF button to toggle system power on/off
Shock	Red Shock button to discharge defibrillator; red LED flashes when defibrillator is fully charged
Menu selection	Two soft buttons located to the left of the display; programmable functionality to make menu selections in programming mode.

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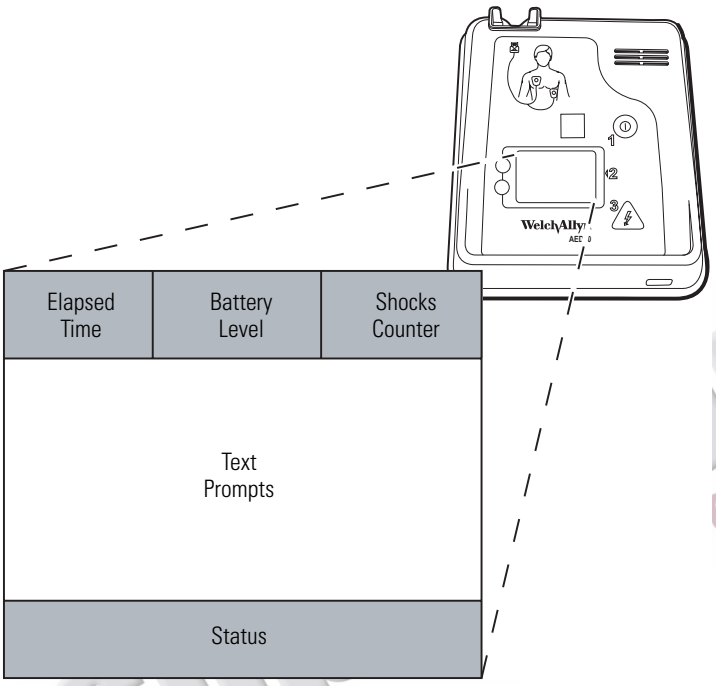
Display

Text prompts, patient data, and event information display on the liquid crystal display (LCD) screen. The display is a backlit monochrome liquid crystal display (LCD) measuring 160 x 100 pixels. The display is divided into five functional areas. Operating information and user instructions display in these areas.



Shocks Counter	Displays the number of shocks administered to the current patient.
Text Prompts	Displays up to three lines of text (user instructions, directions for patient care, error messages). See descriptions below.
Elapsed Time	Displays the time elapsed since the system was powered ON, or time used on current patient. The time format is HH:MM:SS.
Battery Level	Displays battery status icons. See descriptions below.
Status	Displays various system status prompts, such as Charging and Energy Delivered.

Graphical screen icons provide system operational information. The Welch Allyn AED 10 operator or supervisor can use a simple menu-driven structure to set charge protocols and system configurations, set system operating parameters such as display contrast, and select the language used for text and voice.

Text Prompts

Text prompts provide operating information and instructions. The prompts display in the lower half of the LCD above the status window.

ANALYZING	Defibrillator pads are properly connected and the system is accessing the patient's heart rhythm.
ATTACH DEFIB PADS	Attach the defibrillation pads according to the instructions given on the package.
CHARGING	System is automatically charging the defibrillator to the energy level pre-set in the shock protocol.
BEGIN CPR	Begin a CPR cycle.
MOTION DETECTED	System has detected movement of the electrodes or the patient as indicated by inconsistent data readings.
NO SHOCK ADVISED	System has analyzed the patient's heart rhythm and determined that a shockable condition does not exist.
SHOCK ADVISED	System has analyzed the patient's heart rhythm and determined that a shockable condition exists.
SHOCK NOW	Prepare to administer the shock.
STAND CLEAR	Defibrillator is charged and ready for shock. Do not touch or move the patient.

Voice Prompts

The Welch Allyn AED 10 voice prompt feature provides instructional prompts to guide the user through the defibrillation process without relying solely on text prompts.

The Welch Allyn AED 10 provides audio instructions through the built-in speaker to provide operating instruction and assist the user during defibrillation. The voice prompts listed in the following table parallel the text and icon displays shown on the LCD.

Analyzing heart rhythm, do not touch the patient	Defibrillator pads properly attached and connected; assessing heart rhythm
Analyzing interrupted, motion detected	Patient or electrode moved
Apply defib pads to patient's bare chest, connect cable	(at unit power up) Attach electrode pads to the patient and connect cables to the Welch Allyn AED 10
Apply defib pads, connect cable	Defibrillator pads are not properly attached to the patient or properly connected to the Welch Allyn AED 10
Begin CPR	Begin a CPR cycle.
Low battery	Low battery charge. Replace battery.
No shock advised	Shockable condition does not exist
Shock advised	Shockable condition exists
Shock now, press the red button now	Push the red SHOCK button

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Stand clear	Defibrillator charged and ready to shock; do not touch or move patient
Stop CPR	Stop CPR, wait for further instructions
It is safe to touch the patient	Defibrillator shock has been delivered
Shock not delivered	Attempted shock did not deliver any energy to the patient

Battery Level Indicator

Fully charged

Partially depleted

Low

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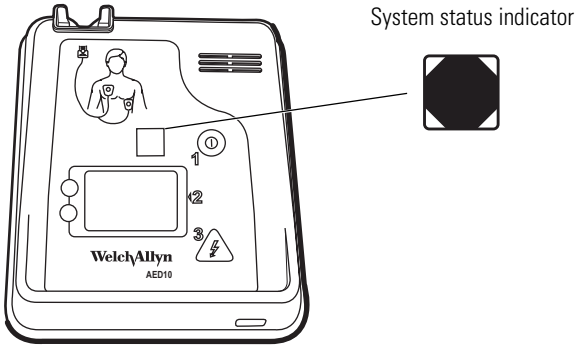
System Status Indicator

The system status indicator display, located in the center of the Welch Allyn AED 10, represents the operational readiness of the battery.



Ready		Battery is properly installed, charged, and system is ready for use.
Do Not Use		System is not ready for use. Battery may not be properly installed, battery charge is too low for effective operation, or system failure.
Flashing		Battery is low and requires changing.

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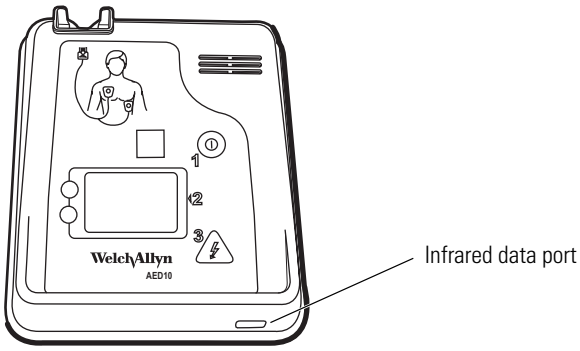
Infrared Data Port

The built-in Infrared Data Port provides a wireless connection to the Welch Allyn IRDA device. (See "Event Documentation", below, for details.)



Event Documentation

The Welch Allyn AED 10 stores event documentation including patient status, ECG traces, and treatment summary. The information is stored in an internal log. Event documentation is time stamped and can be downloaded to a computer and printed through the infrared data port on the Welch Allyn AED 10. The AED 10 IR communication kit with Smartlink Lite Software (002143) or AED 10 Communication Kit with Smartlink Event Pro Software (002169) is required to produce an event report.

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Preparing the Welch Allyn AED 10 for Storage

After each use, any event documentation should be retrieved from the internal log and printed. Any error messages or malfunctions should be reported and corrective actions taken before storing the unit for reuse. Then, the Welch Allyn AED 10 should be inspected, cleaned, used pads should be removed, and a new supply of electrode pads restocked to prepare the unit for its next use. Do not open sealed pads bag until immediately prior to use.

Note To remove the pads, pull the wire upward from the device.

Note DO NOT REUSE PADS.

Store a new set of defibrillation pads in the carrying case electrode storage pocket – located on the inside flap of the AED 10 carrying case. Spare pads can be stored in the exterior pocket of the carrying case. Make sure the pad expiration date can be viewed through the pad window of the carrying case. When preparing your device for storage/ deployment be sure that the status indicator is visible through the round window of the carrying case.

During storage, the Welch Allyn AED 10 performs periodic self-tests including the functionality of the unit and the status of the battery and internal circuitry. A periodic inspection of your device should be performed on a weekly or monthly basis. See "Maintenance" on page 53 for more information.

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Parts List

Welch Allyn AED 10

Part number	Part	Notes
970300	Welch Allyn AED 10 with Orbital Biphasic Waveform	Includes one set of defibrillation pads, battery, and operator's manual.

AED 10 is available in a variety of deployment configurations. Ask your Welch Allyn representative or authorized distributor for more information.

Accessories

Part Number	Part	Notes
001852-2	Welch Allyn Battery Pack	Non-rechargeable LiMnO2 battery
900432	AED 10 Heart Logo Carrying Case with pad expiration date windows, AED status indicator window and EMS info card	Includes storage area for supplies such as spare pads / batteries, prep kit and pediatric energy reducer (acquired separately)
001853	Welch Allyn Multipurpose Defibrillation Pads, One Pair	
001855	Welch Allyn Multipurpose Defibrillation Pads, 10 pair	
980150	Welch Allyn AED 10 Trainer with IR Remote Control, Training Pads and Carrying Case	
001857	Pre-Attached Defibrillation Pads (1 pouch / 2 pads)	Pads sealed in pouch with cable exposed
001858	Pre-Attached Defibrillation Pads (1 box / 10 pair)	Pads sealed in pouch with cable exposed
002173	AED 10 Pediatric Energy Reducer (002168), carrying pouch and instructions for use	For use with AED 10 devices only
002137	Welch Allyn First Responder AED Prep Kit	
002143	SmartLink Lite AED 10 IR Communications Kit	
002169	SmartLink Event Pro AED 10 IR Communications Kit	

Additional supplies and accessories are available for your device. Contract your local Welch Allyn representative or authorized distributor for more information.

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3 Using the Defibrillator

This chapter provides information for using the Welch Allyn AED 10 with a patient. It also provides the instructions for operating the Welch Allyn AED 10 in automated or manual mode and describes the procedures to follow after using the unit.

Caution Read the Safety section at the beginning of this manual before proceeding with this chapter.

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Overview

The Welch Allyn AED 10 is capable of operating in an automated mode. In this mode, the operator must be trained to use the unit and understand the indications and contraindications for use.

Trained Operators

The Welch Allyn AED 10 is intended to treat patients in cardiopulmonary arrest. It is for use in either in-hospital or out-of-hospital arrests. It is intended that the operator is authorized by a physician/medical director, and has the following training skills:

- American Heart Association Heartsaver course, American Red Cross CPR/AED course, NSC CPR and Rescuer Course, or equivalent.
- Training in the use of the Welch Allyn AED 10.

Fibrillation and Defibrillation

Ordinarily the heart produces regular electrical activity—normal sinus rhythm (NSR). Fibrillation is an abnormal heart rhythm that replaces the normal rhythmic contraction of the heart. During fibrillation, irregular cardiac electrical activity causes rapid, uncoordinated twitching movements. As a result, the heart cannot pump blood effectively causing a lack of appropriate circulation and pulse.

Defibrillation is the delivery of a brief, high-energy pulse of electricity to the heart muscle using a device called a defibrillator. Early defibrillation increases the potential to restore the normal cardiac electrical activity and allow the heart's natural pacemaker areas to regain normal function.

The Welch Allyn AED 10, using direct current, applies a brief, high-energy pulse of electricity to the heart to counteract fibrillation of the heart muscle and restore a normal heartbeat.

The Welch Allyn AED 10 will only administer a defibrillation pulse to a patient exhibiting a shockable cardiac rhythm. Shockable rhythms are described in Appendix A. All other rhythms are determined “non-shockable” and the patient is not a candidate for defibrillation. Cardiopulmonary resuscitation (CPR), medication, and supplemental oxygen may also be required to effectively resuscitate the patient.

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Indications and Contraindications for Use

Once the Welch Allyn AED 10 is connected via the defibrillation electrode pads to the patient, the instrument assesses the patient's cardiac status and indicates whether the patient is a candidate for defibrillation. The Welch Allyn AED 10 will only administer a defibrillation pulse (shock) to a patient exhibiting a shockable cardiac rhythm. All other rhythms are non-shockable and the patient is not a candidate for defibrillation. Cardiopulmonary resuscitation (CPR), medication, and supplemental oxygen may also be required to effectively resuscitate a patient. This defibrillator should not be used on patients less than 8 years old or under 25kg (55lbs), unless it is equipped with the accessory AED 10 Pediatric Energy Reducer (Welch Allyn 02173).

Defibrillation may be effective against cardiac arrhythmias such as:

- Cardiac arrest
- Ventricular fibrillation
- Ventricular tachycardia
- Other cardiac rhythms with ventricular rates equal to or greater than 160 beats per minute and amplitudes of at least 0.099 millivolts (mV)

Note The Welch Allyn AED 10 has not been evaluated for cardioversion of atrial fibrillation.

Indications

Prior to using the Welch Allyn AED 10, the patient should be assessed by a trained person. See "Trained Operators" on page 22. If defibrillation with the Welch Allyn AED 10 is indicated, all of the following signs should be present during patient assessment:

- Unconsciousness
- Absence of breathing
- Unresponsiveness (no signs of circulation)

Contraindications

The Welch Allyn AED 10 should NOT be used if the patient exhibits any of the following signs:

- Patient is conscious
- Patient is breathing
- Patient is responsive (has signs of circulation)

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Operating Procedures — Quick Reference

The following instructions provide an experienced operator with the main steps for using the Welch Allyn AED 10. Detailed operating information and procedures are provided in "Operating Procedures – Detailed Information" on page 25. Users should refer to the Quick Reference Guide included with the Welch Allyn AED 10.

Assess the Patient

Verify that the patient is unconscious, is not breathing, and unresponsive (has no signs of circulation). Even if the victim takes occasional gasps, rescuers should suspect that cardiac arrest has occurred. Proceed with treatment.

Attach Electrodes

1. Apply pads to patient's bare chest.
2. Connect the cable to the AED 10.

Start the Welch Allyn AED 10 and Deliver a Shock

1. Push the green **ON/OFF** button located at the upper right corner of the Welch Allyn AED 10 next to the large number "1".
2. Listen to voice prompts and read text instructions on the screen next to the large number "2".
3. If prompted, press the red **Shock** button next to the large number "3".

Begin CPR – Start with Chest Compressions

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Operating Procedures – Detailed Information

The Quick Reference operating procedure in the preceding subsection provides the main steps for operating the Welch Allyn AED 10:

1. Assess the Patient.
2. Attach the Electrodes and Connect the Cable.
3. Start the Welch Allyn AED 10.
4. Analyze the Patient's Heart Rhythm.
5. Deliver the Shock (if prompted, press the red button).
6. Perform CPR.

For each step, detailed operating information or procedures follow.

Assess the Patient

Before using the Welch Allyn AED 10, assess the patient's condition. Use the unit only if all of the following patient signs are present:

- Unconsciousness
- Absence of breathing
- Unresponsiveness (no signs of circulation)

Attach the Electrode Pads and Connect the Cable

For defibrillation to be effective, it is important to correctly place the pads on the patient and connect the electrodes to the Welch Allyn AED 10.

Before applying pads to the patient's chest be sure to:

- Remove all clothing covering chest
- Wipe off any water, moisture, or perspiration
- Press the pads firmly to make sure they adhere securely to the chest.

Note To remove pads, pull the wire upward from the device.

Note DO NOT REUSE PADS.

WARNING Excessive body hair may affect the operation of the electrodes or cause skin burns on the patient. Remove body hair as needed to ensure that the electrode pads make proper contact with the patient's chest.

To attach electrodes and connect the cable

1. Open the package containing the defibrillation pads and cable.
2. Peel off the backing from the electrode pad labeled RA. Place this pad just below the patient's right collarbone (sternum) as illustrated on the AED 10 pad placement illustration.

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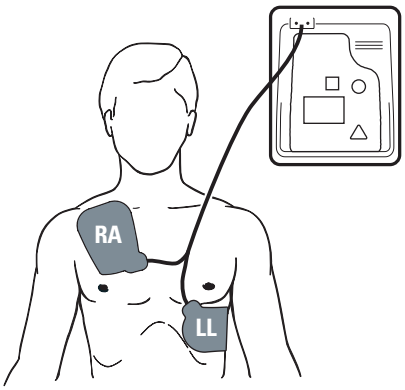
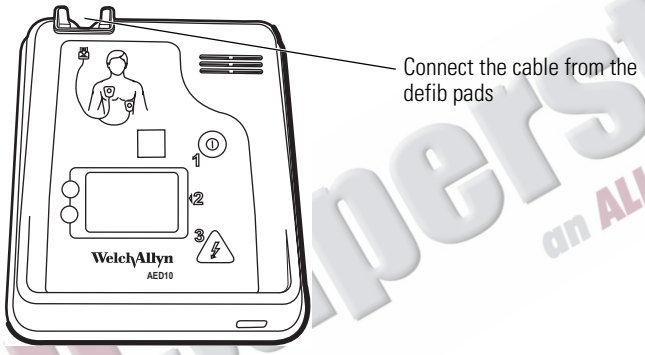


3. Peel off the backing from the electrode pad labeled LL. Place this pad over the ribs on the patient's left side below the breast (apex) as depicted on the pad placement illustration.
4. Plug the pad connector into the Welch Allyn AED 10 on the left side of the unit.

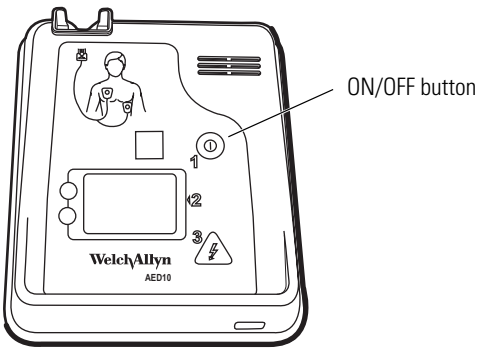


Note If the pads are not properly applied or if the cable is not properly connected to the Welch Allyn AED 10, it will alert the user with text and voice.

"Apply pads to patient's bare chest and connect the cable."

Start the Welch Allyn AED 10

Push the green ON/OFF button next to the large number "1" to power-on the Welch Allyn AED 10.



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Analyze the Patient's Heart Rhythm

When the pads are properly applied and connected, the Welch Allyn AED 10 announces and then automatically analyzes the patient's heart rhythm to determine if a shock is indicated.

"Analyzing heart rhythm. Do not touch the patient."

Caution Do not touch or move the patient while the Welch Allyn AED 10 is analyzing the heart rhythm.

Rhythm analysis takes approximately 8 to 16 seconds. During this time, any movement, including CPR and patient transport, may interrupt analysis and delay the defibrillation prompts. Text and voice prompt will alert user if patient or electrodes move:

"Analyzing interrupted. Motion detected."

Deliver Shock

The Welch Allyn AED 10 will only administer a shock to a patient exhibiting a shockable cardiac rhythm. All other rhythms are determined "non-shockable" and therefore the patient is not a candidate for defibrillation.

If it is not a shockable condition, the Welch Allyn AED 10 alerts the user with text and voice.

"No shock advised."

If a shockable condition is detected, the Welch Allyn AED 10 alerts the user with text and voice.

"Shock advised."

To deliver a shock

1. Make sure the **Shock** button next to the large number "3" is flashing. This indicates that the unit is properly charged.

WARNING Make sure no one is touching the patient before you press the Shock button. Loudly announce, "**Stand back! Do not touch the patient.**" and look down the entire length of the patient to ensure there is no contact with a bystander or conductive surface before pressing the Shock button.

"Stand clear."

"Shock now. Press the red button now."

2. Press **Shock** to deliver a shock.

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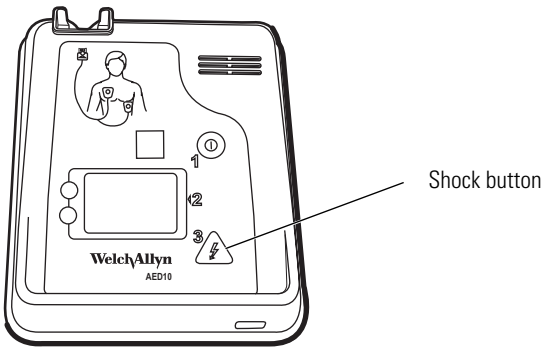

Note The Welch Allyn AED 10 does not allow the operator to charge or discharge the defibrillator unless a shockable rhythm is detected.

After delivering a shock, the Welch Allyn AED 10 prompts for immediate CPR.

Note In the 3-shock cycle configuration, the AED 10 continues to analyze the heart rhythm and determine whether additional shocks are indicated.

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Defibrillator Disarm

If the defibrillator is charged and the Shock button is not pressed, the Welch Allyn AED 10 must be disarmed.

- The defibrillator discharges automatically in 30 seconds. After 25 seconds, a warning tone indicates that the defibrillator will disarm automatically.
- The operator can press the ON/OFF button and turn off the defibrillator.

Check the Patient's Condition and Perform CPR

If the heart rhythm is not treatable with defibrillation, the Welch Allyn AED 10 displays and announces the message No Shock Advised.

"No shock advised."

The Welch Allyn AED 10 will direct the operator to perform cardiopulmonary resuscitation (CPR) to effectively resuscitate the patient.

"Begin CPR."

Perform cardiopulmonary resuscitation (CPR) in accordance with the procedures and techniques presented in your CPR training.

In the 3-shock mode configurations, the Welch Allyn AED 10 can be configured to suspend the heart rhythm analysis during the CPR interval (3-Shock/CPR) or provide a background heart rhythm analysis during CPR (3-Shock/Analyze).

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Shock Mode

The Welch Allyn AED 10 can be configured in one of three rescue modes:

1 Shock/CPR

(Factory preset). During a shockable event, the AED 10 will deliver one shock followed by a cycle of CPR. A CPR cycle will begin immediately after the delivery of a defibrillation shock or after a non-shockable event. During the CPR cycle, the Welch Allyn AED 10 will suspend patient heart rhythm analysis - promoting an uninterrupted cycle of CPR.

3 Shock/CPR

(Traditional three shock sequence). During a shockable event, the AED 10 will deliver one shock followed by an immediate analysis of the patient's heart rhythm. After delivering a shock, the Welch Allyn AED 10 continues to analyze the heart rhythm and determines whether additional shocks are indicated. The CPR cycle begins after a "No Shock Advised" prompt or after delivering three consecutive shocks. During the CPR cycle, the Welch Allyn AED 10 will suspend patient heart rhythm analysis - promoting a complete and uninterrupted cycle of CPR.

3 Shock/Analyze

Like the "3 shock/CPR" mode, the AED 10 will deliver one shock followed by an immediate analysis of the patient's heart rhythm while in a shockable event. The AED 10 will also continue to analyze the heart rhythm and determine whether additional shocks are indicated. The CPR cycle begins after a "No Shock Advised" prompt or after delivering the third shock.

However, during the CPR cycle the Welch Allyn AED 10 will continue to analyze the patient heart rhythm. Should the Welch Allyn AED 10 detect the presence of a shockable rhythm during the CPR cycle, the user will be prompted to stop CPR. The AED 10 will analyze patient heart rhythm and if need, prompt the user to deliver a shock. A "No Shock Advised" text prompt will continue to flash on the display - accompanied by an audible tone every minute until a shockable rhythm is detected.

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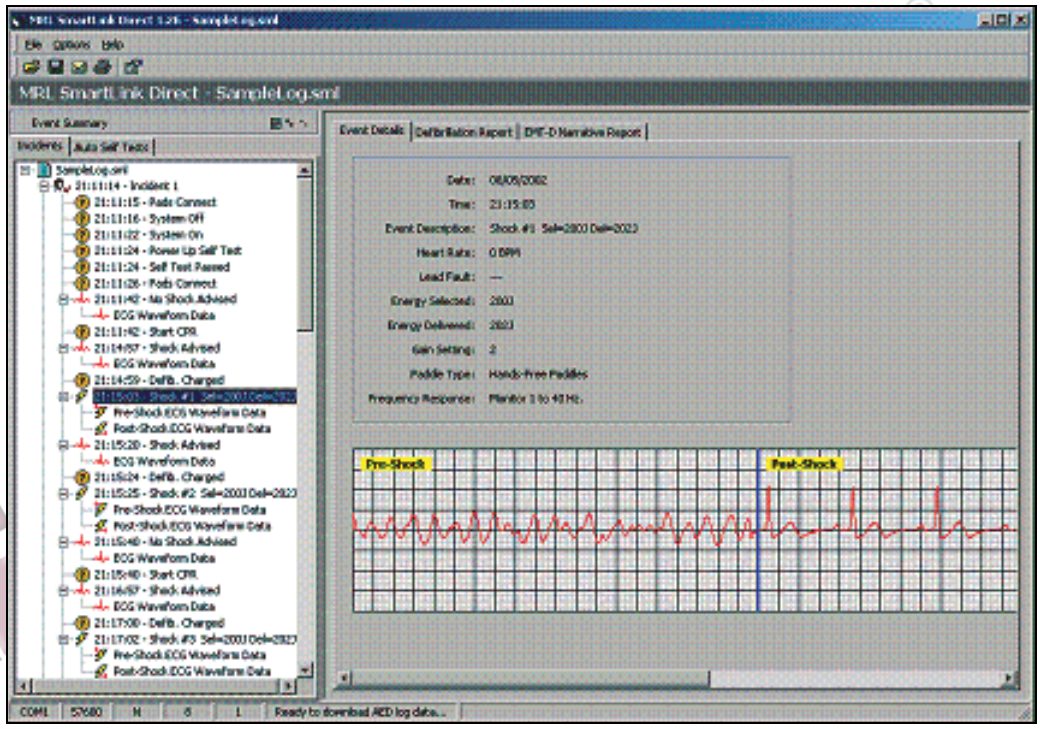
Post-Use Procedures

Working with the Internal Log

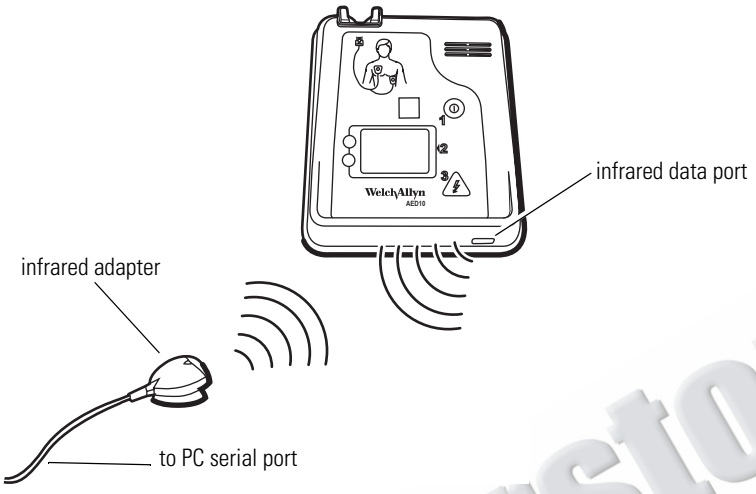
After each use, the Welch Allyn AED 10 internal log can be downloaded to a PC via the infrared data port. Reports can be generated with one of two Welch Allyn communication kits: SmartLink Lite software and SmartLink Event Pro software.

The SmartLink Lite communication kit can be used to produce a hardcopy report from your desktop printer using your Windows based PC. SmartLink Event Pro provides expanded features such as patient treatment data review, ECG traces, analysis results, CPR information, and an EMT-D Narrative Report template. Reports can be saved, printed, and sent via e-mail.



Transmitting the Internal Log via the Infrared Data Port

Transmitting data via the infrared data port is fast and easy. Using the Welch Allyn AED 10 Infrared Communications Kit (Part No. 002143), simply connect the infrared adapter cable to a PC serial communication port. Next, align the infrared adapter to the infrared data port on the AED 10.



Note Keep the infrared data port and adapter cable roughly 6 to 10 inches apart.

Note The bit rate of the AED 10 must be the same as the bit rate set in SmartLink to transfer the log. Refer to "Setting the Bit Rate" on page 51.

Start the SmartLink program on the PC and access the AED 10 main menu by holding down the lower menu soft key while powering on the unit. Select the Log Menu and then select "Smartlink." The "Smartlink" selection flashes during data transfer.

Note See "Setting Up the Internal Log" on page 42 and "Transmitting or Clearing the Internal Log" on page 41 for more information.

The Welch Allyn AED 10 also stores a service log used for keeping track of system information. If any error messages or malfunctions occur, the service log can be transferred to SmartLink and then sent to Welch Allyn service technicians for review. The internal log retains its data after transmitting to the PC and may contain data from multiple incidents. Therefore, it is recommended that the user clear the internal log after successfully transferring its contents. Any error messages or malfunctions should be reported and corrective actions taken before storing the unit for reuse.

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Storing the Welch Allyn AED 10 for Reuse

After each use, the Welch Allyn AED 10 should be inspected and cleaned, with a new supply of electrode pads restocked to prepare the unit for its next use. Any event documentation should be retrieved from the internal log and printed.

Note When using the Welch Allyn AED 10 carrying case, store new electrode pads to ensure proper viewing of the system status indicator.

During storage, the Welch Allyn AED 10 performs periodic self-tests including the functionality of the unit and the status of the battery and internal circuitry. A more detailed test of defibrillator operation and battery status should be performed on a regular basis. See "Maintenance" on page 53 for more information.

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4 Programming

This chapter explains how to set the basic system operating options through the Main Menu. It also provides information on accessing and setting the advanced system operating options using the Supervisor Menu.

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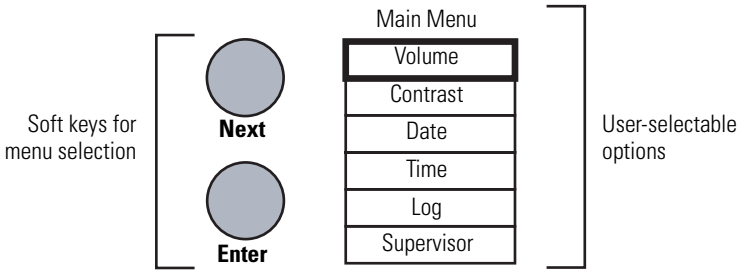
Menu Structure Diagram



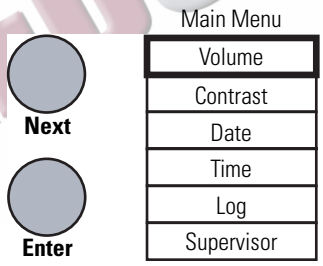
Menu Structure Overview

The operating options are available to the operator through a simple menu structure. The basic system operating options are accessed through the Main Menu. The advanced system operating options are accessed through the Supervisor Menu.

Accessing the Main Menu from Startup

To access the Main Menu, hold down the lower **Enter** soft key while powering-on the unit. A menu similar to the above diagram will appear on the left side of the LCD display. Although unlabeled on the front panel/decal of the AED 10, the display will turn on and identify the keys while in menu mode. To exit, shut off power.

Use the **Next** soft key on the left side of the LCD display to move from one menu selection to the next. The selected menu item is highlighted by a dark box. Press the **Enter** button to select the highlighted menu item.



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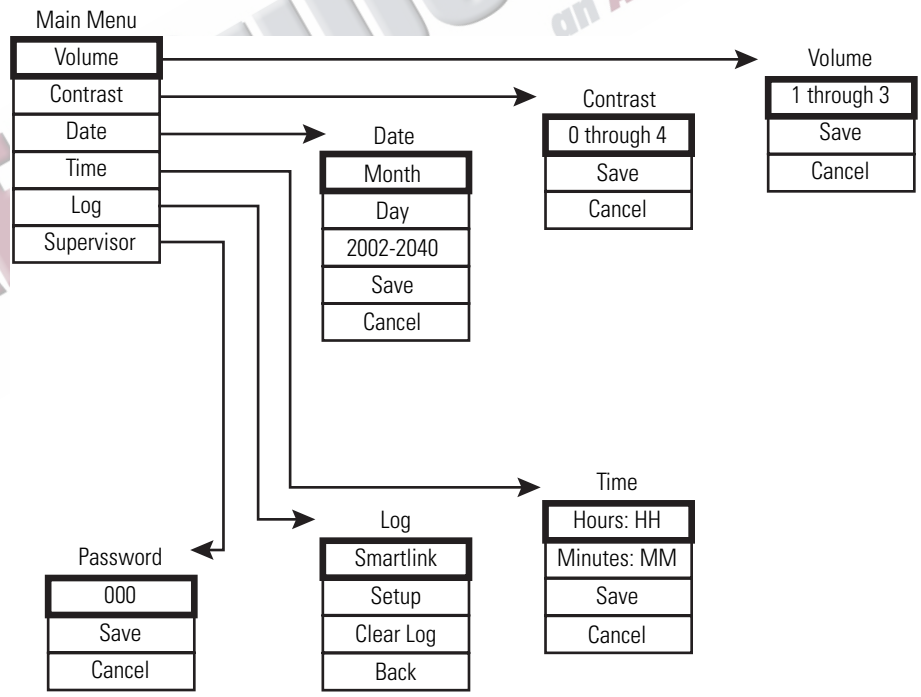
Main Menu Selections

Volume	Adjust the volume level.
Contrast	Adjust the LCD contrast.
Date	Display the current date; set and save the date (month, day, year).
Time	Display the current time; set and save the time (hour, minute).
Log	Allows the user to: 1. Clear the existing event log, or 2. Setup the infrared port to transfer the log to the WA SmartLink tools.
Supervisor	Enter the password code, using the buttons below the Menu Bar, to display the selections.

For each menu item selected, the corresponding options replace the Main Menu on the left side of the LCD display.

If Supervisor is selected, the user must enter the correct supervisor password to enter the Supervisor Menu selection screen.

Main Menu Structure Overview



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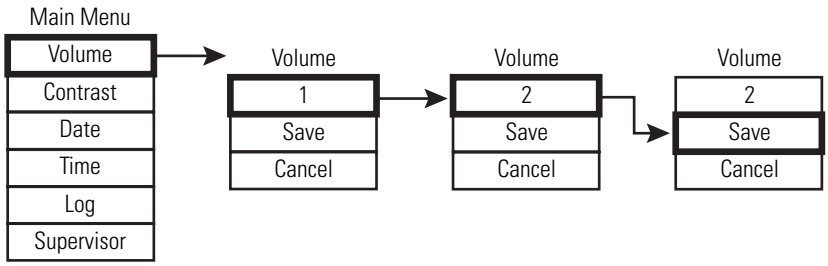
Adjusting the Volume

The volume of the voice prompts through the Welch Allyn AED 10 speaker can be adjusted. There are three preset volume levels available. Use the volume screen and the menu selection button below the menu bar to change the volume of the voice prompts.



To adjust the volume

1. Access the **Main Menu**. Select **Volume** to display the **Volume Menu**.
2. Press the **Next** soft key to change the volume level. As sound volume values are selected, the sound volume will change immediately and a "Beep" sound will be heard.
3. Highlight **Save** by pressing **Enter** after the desired volume level has been selected. Press the **Enter** soft key again to confirm the change and return to Main Menu.
4. To leave the volume at its original level, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Main Menu.

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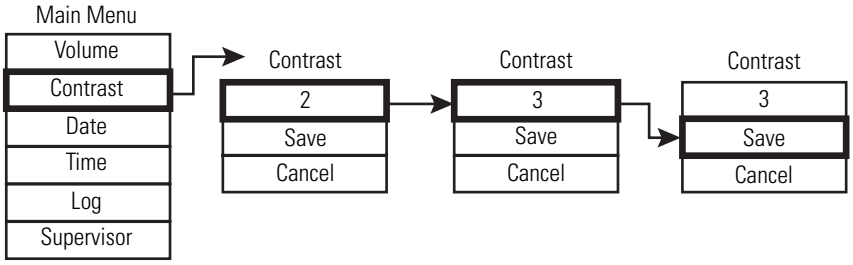
Adjusting the Contrast

The contrast of the Welch Allyn AED 10 liquid crystal display can be adjusted. There are five pre-set contrast levels available. Use the Contrast Menu and the Next and Enter soft keys to change the LCD contrast.

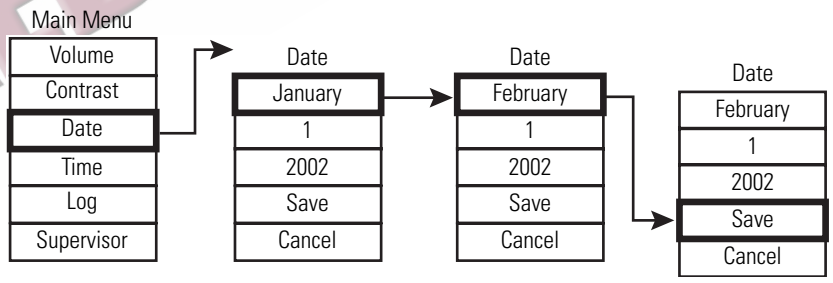


To adjust the LCD contrast

1. Access the **Main Menu**. Select **Contrast** to display the **Contrast Menu**.
2. Press the **Next** soft key to change the contrast of the LCD. The display contrast will change as the displayed value is incremented.
3. Highlight **Save** by pressing **Enter** after the desired contrast has been selected. Press the **Enter** soft key again to confirm the change and return to the Main Menu.
4. To leave the contrast at its original level, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Main Menu.

Setting the Date

Use the Date Menu to change the date. Use the Next and Enter soft keys to change the date displayed.



To set a new date

1. Access the **Main Menu**. Select **Date** and display the **Date Menu**.
2. Highlight a field (month, day or year) by using the **Enter** soft key. Press the **Next** soft key to change the value of the field.
3. Highlight **Save** by pressing **Enter** after the desired date has been selected. Press the **Enter** soft key again to confirm the change and return to the Main Menu.
4. To leave the date as it was originally, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Main Menu.

Note Setting the date begins a new patient record in the entry log.

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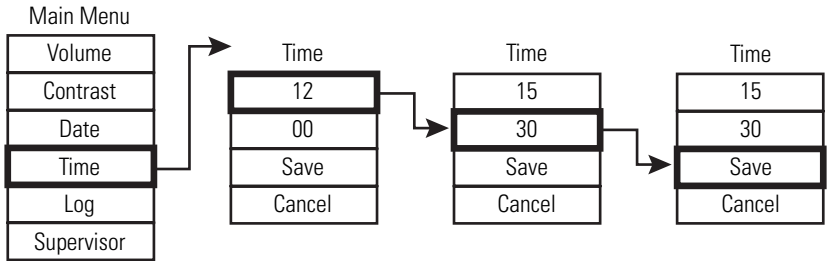
Setting the Time

The Welch Allyn AED 10 time-stamps events and saves them to the internal log. A 24-hour clock is used for time displays (e.g., 15:30 is used for 3:30 p.m.). Use the Time Menu and the Next and Enter soft keys to change the hours and minutes.



To set a new time

1. Access the **Main Menu**. Select **Time** to display the **Time Menu**.
2. Highlight a field (hours or minutes) by using the **Enter** soft key. Press the **Next** soft key to change the value of the field.
3. Highlight **Save** by pressing **Enter** after the desired time has been selected. Press the **Enter** soft key again to confirm the change and return to the Main Menu.
4. To leave the time as it was originally, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Main Menu.

Note Setting the time forces a new patient into the entry log.

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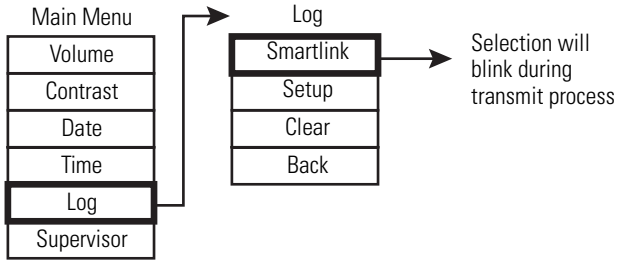
Transmitting or Clearing the Internal Log

A complete treatment summary including time-stamped status events, records of analysis results and pre- and post-shock ECG samples are stored in the internal log. This information can be transferred to a personal computer via the AED 10's infrared data port. Also, this data can be cleared from the log. See "Working with the Internal Log" on page 31 for detailed information on Log functionality.



To transmit information stored in the Log

1. Access the **Main Menu**. Select **Log** to display the **Log Menu**.
2. Transmit or clear the Log by using the **Next** soft key to select the desired action. Press the **Enter** soft key to take that action. The selection will blink during this process, then the main menu will reappear.
3. To exit to the Main Menu and not transmit or clear the log, use the **Next** soft key to highlight **Cancel**. Press **Enter** to return to the Main Menu.

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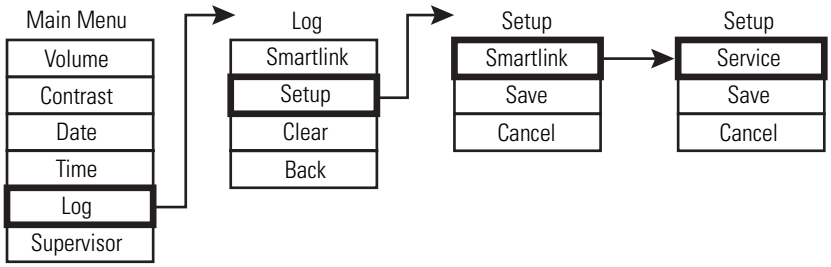
Setting Up the Internal Log

The Welch Allyn AED 10 has two modes of transmitting the internal log to a PC. Both methods utilize the infrared data port located on the front of the unit. To select which method to use, the user must access the Log: Setup Menu.



To change transmit mode

1. Access the **Main Menu**. Select **Log** to display the **Log Menu**.
2. Press the **Next** soft key to highlight **Set Up**. Press the **Enter** soft key to display the **Log: Setup Menu**.
3. Press the **Next** soft key to change the transmit mode.

   If using the SmartLink program, select **SmartLink**.

   If transferring the service log, select **Service**. (See "Working with the Internal Log" on page 31 for more information.)
4. Highlight the **Save** box and press **Enter** to save the changes and return to the Log Menu.
5. To leave the transmit mode as it was originally, highlight the **Cancel** box and press **Enter** to return to the Log Menu.

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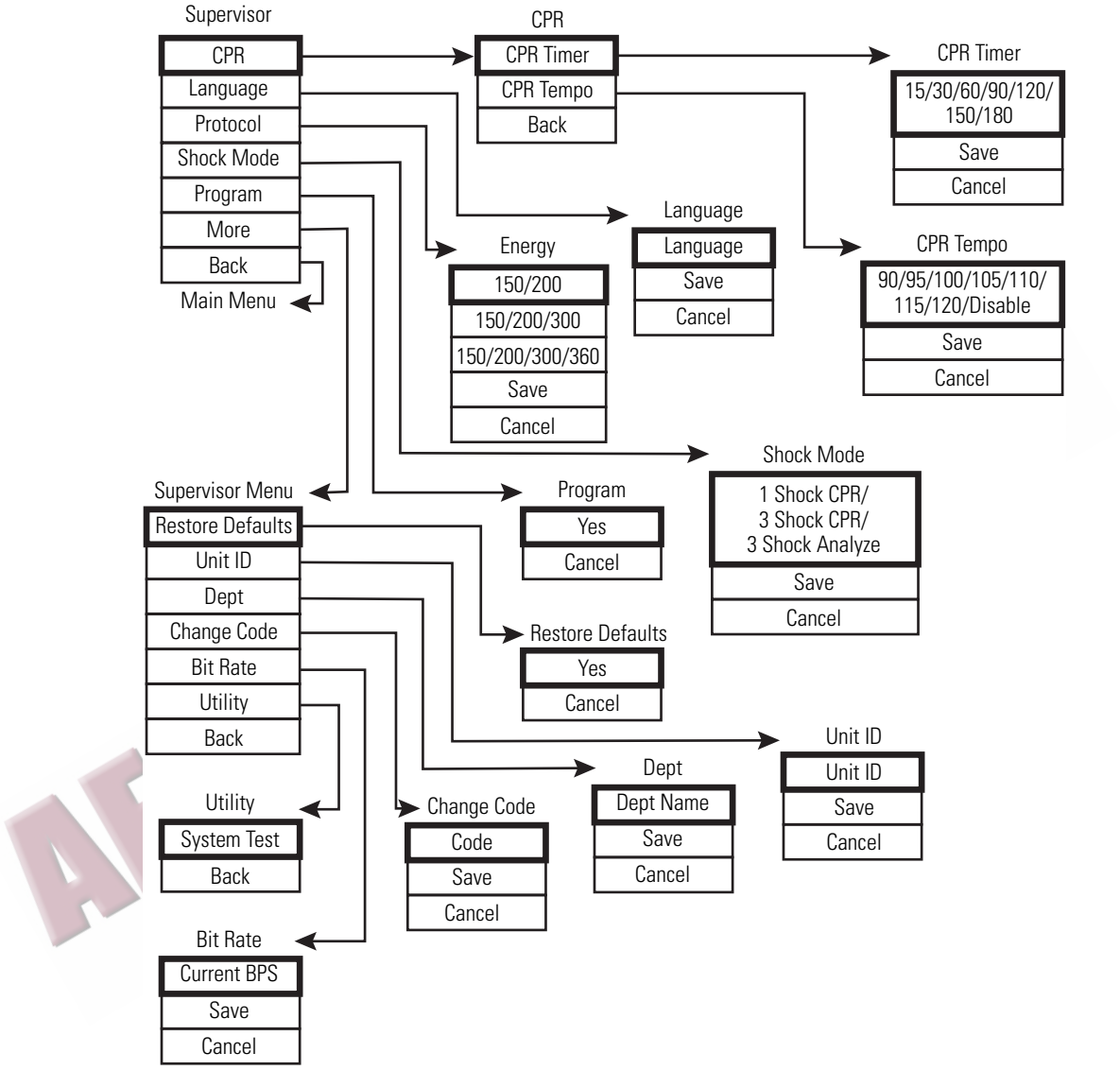
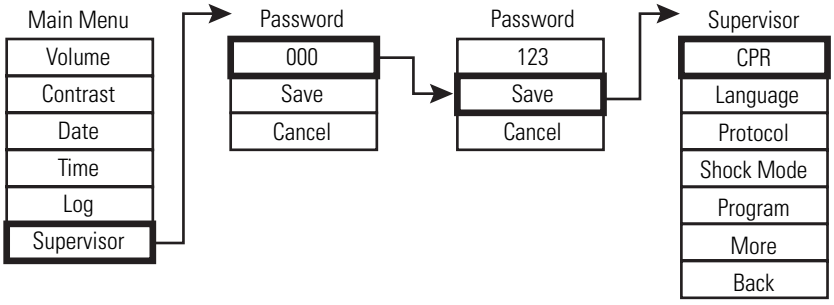
Supervisor Menu

Supervisor Menu Structure Overview



Accessing the Supervisor Menu

The Supervisor Menu is accessed from the Main Menu.

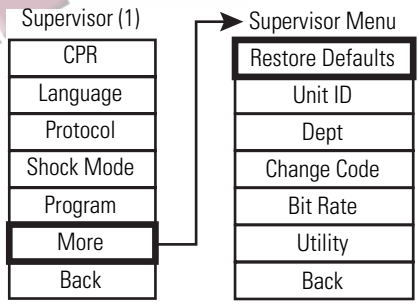


To access the Supervisor Menu

1. While in the **Main Menu**, press the **Next** soft key to highlight **Supervisor**, and then press the **Enter** soft key to go to the **Password Menu**.
2. Enter the Password by using **Next** to scroll to the appropriate number and use **Enter** to shift to the next digit. After the third number has been selected, highlight Save by pressing **Enter**.
3. Press **Enter** again while in the Save box. If the password is correct, the Supervisor Menu will appear. If the password is incorrect, the Main Menu will appear.
4. To exit the Password prompt, press **Next** when the Save box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Main Menu.

Note The default supervisor password is 1 2 3.

Supervisor Menu Items



CPR	Set the value for CPR Timer and/or CPR Tempo.
Language	Select text and audio language. The Welch Allyn AED 10 will reboot into automated mode to activate selected language.
Protocol	Select the energy level protocol. Default protocol is 200, 300, 360 Joules.
Shock Mode	Selects among 1 Shock CPR (default), 3 Shock CPR, or 3 Shock Analyze mode.

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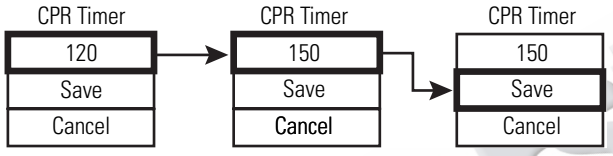
Program	Allows the user to update to the current version of Welch Allyn AED 10 software via the infrared port.
Restore Defaults	Reset the Welch Allyn AED 10 options to factory defaults.
Unit ID	Set the Welch Allyn AED 10's Unit ID.
Dept	Set the Welch Allyn AED 10's Department Name.
Change Code	Set supervisor password numbers.
Bit Rate	Allows the user to change the bit rate of the infrared port.
Utility	Opens the Utility Menu

Setting the CPR Timer

The CPR timer begins if a "No Shock Advised" decision is made to time the appropriate length that CPR should be performed.



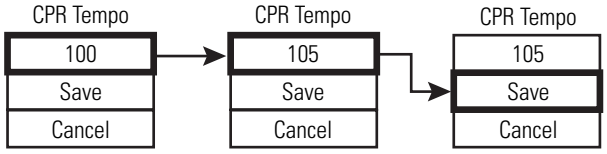
To set the CPR Timer

1. Access the **Supervisor Menu** screen. Highlight **CPR** and press **Enter**. Select **CPR Timer** to display the **CPR Timer Menu**.
2. Press the **Next** soft key to scroll through CPR timer lengths.
3. Highlight Save by pressing **Enter** after the desired time has been selected. Press the **Enter** soft key again to confirm the change and return to the CPR Menu.
4. To leave the time as it was originally, press **Next** when the Save box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the CPR Menu.

Note Available CPR timer values are 15, 30, 60, 90, 120 (default), 150, and 180 seconds.

Setting the CPR Tempo

The CPR Tempo is the rate at which a tone plays when the CPR Timer is running.



To set the CPR Tempo

1. Access the **Supervisor Menu** screen. Highlight **CPR** and press **Enter**. Select **CPR Tempo** to display the **CPR Tempo Menu**.
2. Press the **Next** soft key to scroll through CPR tempo values.

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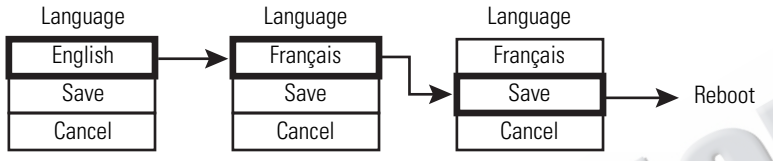
3. Highlight Save by pressing **Enter** after the desired tempo has been selected. Press the **Enter** soft key again to confirm the change and return to the CPR Menu.
4. To leave the tempo as it was originally, press **Next** when the Save box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the CPR Menu.

Note Available CPR tempo values are 90, 95, 100 (default), 105, 110, 115, 120, and Disable.

Selecting a Language (Software Revision 2.0 or later)

The language used for text on icons, screen displays, and voice prompts can be changed on the Welch Allyn AED 10.



To select a different language

1. Access the **Supervisor Menu**. Select **Language** to display the **Language Menu**.
2. Press the **Next** soft key until the desired language is displayed.
3. Highlight Save by pressing **Enter** after the desired language has been selected. Press the **Enter** soft key again to confirm the change.
4. To leave the language as it was originally, press **Next** when the Save box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Supervisor Menu.

Note Changing the language will cause the AED 10 to reboot into automated mode.

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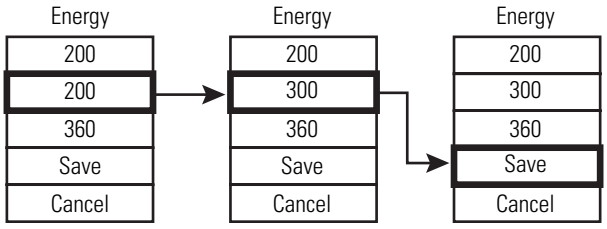
Setting the Energy Protocol

The Welch Allyn AED 10 energy protocol provides a sequence of three defibrillator shocks. The default protocol setting is 200 Joules, 300 Joules, and 360 Joules for the first, second, and third shocks, respectively. However, the energy level for each shock is changeable.



To set a new energy protocol

1. Access the **Supervisor Menu**. Select **Protocol** to display the **Protocol Menu**.
2. Highlight a field (first, second, or third shock) by using the **Enter** soft key. Press the **Next** soft key to change the value of the energy for that shock.
3. Highlight Save by pressing **Enter** after the desired energies have been selected. Press **Enter** again to confirm the change and return to the Supervisor Menu.
4. To leave the energy protocol as it was originally, press **Next** when the Save box is highlighted to select the **Cancel** box. Press **Enter** to return to the Supervisor Menu.

Selectable Shock Energies for 3-Shock Protocol		
First Shock	**Second Shock**	**Third Shock**
150 J	150 J	150 J
200 J	200 J	200 J
	300 J	300 J
		360 J

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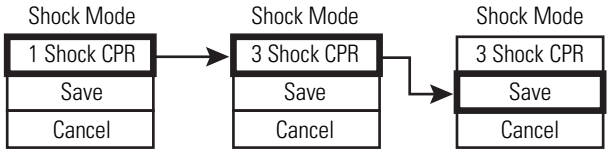
Setting the Shock Mode

The Welch Allyn AED 10 allows to choose from 3 different shock modes. These modes are 1 Shock CPR (goes into CPR mode after every shock), 3 Shock CPR (goes into CPR mode after every 3 shocks), and 3 Shock Analyze (for a non-shockable heart rhythm, continuously analyzes in the background).



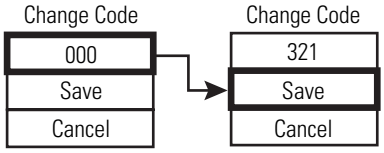
To set Shock Mode

1. Access the **Supervisor Menu** screen. Select **Shock Mode** to display the **Shock Mode Menu**.

2. Press the **Next** soft key to select different mode.
3. Highlight Save by pressing **Enter** after the desired selection has been made. Press the **Enter** soft key again to confirm the change and return to the Supervisor Menu.
4. To leave the selection as it was originally, press **Next** when the Save box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Supervisor Menu.

Changing the Supervisor Password

Access to the Supervisor Menu is protected by a password. The supervisor can change this password.



To change the supervisor password

1. While in the **Supervisor Menu**, press the **Next** soft key to highlight **Change Code**, then press the **Enter** soft key to go to the **Change Code Menu**.
2. Enter the desired new Password by using **Next** to scroll to the appropriate number and use **Enter** to shift to the next digit. After the third number has been selected, highlight Save by pressing **Enter**.
3. Press **Enter** again while in the Save box to save the new password.
4. To exit the Change Code prompt without changing the password, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Supervisor Menu.

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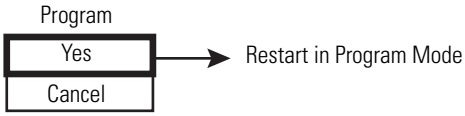
Programming the AED 10

Due to software upgrades or changes in functionality, the Welch Allyn AED 10 may require reprogramming at some time in its service life. In order to program the AED 10, the user must enter programming mode by selecting Program from the Supervisor Menu.

Note Programming the AED 10 should only be performed by qualified sales or service representatives.



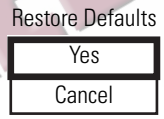
To program the AED 10

1. Access the **Supervisor Menu** screen. Select **Program** to display the Program Menu.
2. Press the **Enter** soft key to restart the unit in program mode.
3. To leave the program as it was originally, press **Next** when the **Yes** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Supervisor Menu.

Note After reprogramming the AED 10, the battery must be removed to turn off the power. When the battery is reinserted, the AED 10 will perform a self-test and then power off.

Restoring the Factory Default Settings

The Welch Allyn AED 10 has the option to revert all user-configurable settings back to the original factory settings. Using this option completely erases all settings, including language, which may have been set by the supervisor.



To restore factory defaults

1. Access the **Supervisor Menu**. Select **Restore Defaults** to display the **Restore Defaults Menu**.
2. The **Yes** box will be highlighted. To restore defaults, press **Enter**.
3. To not restore defaults, press **Next** to highlight **Cancel**. Press **Enter** to return to the Supervisor Menu.

Table 1. Factory default settings

Parameter	Default setting
Volume	3
Password	123
CPR Timer	120

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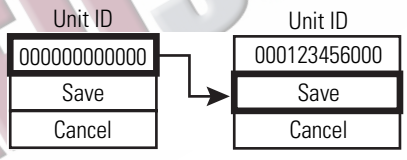
Table 1. Factory default settings

Parameter	Default setting
Language	English US
First energy protocol	200
Second energy protocol	300
Third energy protocol	360
Self test counter	0
ECG Counter	0
LOG setup	DEBUG
CPR tempo	100
Shock counter	0
Total energy	0
Shocks delivered	0
Elapsed time	0
Shock mode	1 shock CPR

Setting the Unit ID

The supervisor has the ability to assign a specific Unit ID number to the Welch Allyn AED 10. The AED 10 includes this ID number when reporting events so that it can be correctly identified among other AEDs. The Unit ID and the department name can be sent to the SmartLink application when transferred by the user through the IR port (see "Transmitting the Internal Log via the Infrared Data Port" on page 32).



To set Unit ID

1. While in the **Supervisor Menu**, press the **Next** soft key to highlight **Unit ID**, and then press the **Enter** soft key to go to the **Unit ID Menu**.
2. Enter the desired Unit ID by using **Next** to scroll to the appropriate number and use **Enter** to shift to the next digit. After the last character has been selected, highlight **Save** by pressing **Enter**.
3. Press **Enter** again while in the **Save** box to save the new Unit ID.
4. To exit the Unit ID prompt without changing it, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Supervisor Menu.

Note There are 12 available characters for the Unit ID.

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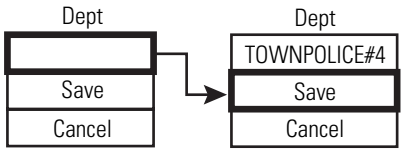
Setting the Department Name

The supervisor has the ability to assign a specific department name to the Welch Allyn AED 10. The AED 10 includes this department name number when reporting events so that it can be identified among other AEDs.



To set department name

1. While in the **Supervisor Menu**, press the **Next** soft key to highlight **Dept**, and then press the **Enter** soft key to go to the **Department Menu**.
2. Enter the desired department name by using **Next** to scroll to the appropriate number, letter, or symbol and use **Enter** to shift to the next space. After the last character has been selected, press **Enter** until **Save** is highlighted.
3. Press **Enter** again while in the Save box to save the new Dept name.
4. To exit the Dept name prompt without changing it, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Supervisor Menu.

Note There are 12 available characters for the Department name.

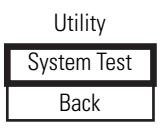
Setting the Bit Rate

The supervisor can change the bits per second at which infrared port of the AED 10 communicates.

1. While in the **Supervisor Menu**, press the **Next** soft key to highlight **Bit Rate**, and then press the **Enter** soft key to go the **Bit Rate Menu**.
2. Press the **Next** soft key to change the bit rate to the appropriate number. After the appropriate number appears press the **Enter** soft key.
3. Press the **Enter** soft key to save the new bit rate.
4. To exit the Bit Rate menu without changing the bit rate, press **Next** when the **Save** box is highlighted to select the **Cancel** box. Press the **Enter** soft key to return to the Supervisor Menu.

Utility Menu

The Utility menu allows access to the System Test function. When selected, the System Test will speak all the voice phrases for the selected language:



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1. Access the **Supervisor Menu** screen. Select **Utility** to display the **Utility Menu**.
2. Press the **System Test** key.
3. At the completion of all the voice phrases, press the **Next** key to select **Back** box. Leave the Utility menu by pressing the **Enter** key with the **Back** box highlighted.

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5 Maintenance

This section contains information on inspecting, maintaining, cleaning, and servicing the Welch Allyn AED 10.

Inspection 54
- Automatic Self-Test 54
- Inspecting for Damage 55
- Service and Repair 55

Maintenance Schedule 56
- General 56
- Checklists for Preparedness 56
- Operator's Checklist 57

Cleaning and Disinfecting the Welch Allyn AED 10 58

Recycling Defibrillator Components 59
- Within the European Union 59
- Outside the European Union 59

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Inspection

To ensure the readiness and optimum working condition of the Welch Allyn AED 10, the unit should be inspected weekly or monthly, depending on the frequency of its use. The checks outlined in the operator checklists should be planned according to the inspection schedule outlined below.

Frequency of Use	Inspection Schedule
Monthly	Weekly
Infrequently, such as once a year	Monthly

Also, new pads or other accessories should be checked for compatibility with the Welch Allyn AED 10 when they are first received.

Note If the Welch Allyn AED 10 is used more than once per month, it is recommended that authorized service personnel perform a periodic inspection servicing at least once per year.

Automatic Self-Test

The AED 10 will automatically perform a weekly self-test while in standby mode with a battery inserted. The AED 10 will also continuously monitor battery level. During weekly self-test, the following tests are performed: battery, main processor, stuck key, internal circuitry, ECG acquisition system, and defibrillator. If a failure occurs during weekly self-test, it will be identified on the display accompanied by an audible notification.

Once the weekly self-test failure occurs, the AED 10 will turn itself on every two hours providing six audible notifications spaced 30 seconds apart. Powering up the AED 10 using the ON button will reset the hourly notification.

If a LOW BATTERY is detected during the self test for two consecutive weeks, the unit will wake itself up 30 seconds after the weekly self test executed and provide a single beep followed by the voice prompt "LOW BATTERY." The AED 10 will turn itself off and wake up 30 seconds later to repeat the beep and the "LOW BATTERY" phrase.

The AED 10 will then go to sleep for 18 hours before restarting the beep and voice prompt cycle listed above. The cycle will repeat for approximately two weeks or until the AED 10 is powered up by the user to address the issue.

After two weeks, the AED 10 will stop waking up to deliver the beep and "LOW BATTERY" notifications and will revert to the standard weekly self test process where it will only supply a failure beep and tone at the end of the weekly test.

If the failure was a fatal error other than a low battery, the unit will act the same as described above, except the two beep and LOW BATTERY notifications will be replaced by six dual beep cycles, each 30 seconds apart. These six dual beep notifications will be repeated every 18 hours for approximately two weeks, or until the AED 10 is powered up by the user to address the issue.

If both a low battery and another fatal error are present during the self test, the user will get both audible notifications described above.

The user can stop these notifications by powering up the unit and addressing the problem.

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If a self-test failure is detected the system status indicator will display the red DO NOT USE indicator. If the failure was only a low battery, the indicator will flash rather than a solid DO NOT USE indicator.

Note The user MUST power the AED 10 on via the power button to clear a low battery error. Simply replacing the battery will not always clear the fault.

You can press the ON button to power-up the Welch Allyn AED 10 and automatically perform a self-test. At power-up, the following tests are performed: battery, main processor, stuck key, internal circuitry, ECG acquisition system, and defibrillator.

Note Frequently powering the AED 10 on will reduce battery life.

Inspecting for Damage

Inspect the Welch Allyn AED 10 and battery. Look for signs of damage. See "Checklists for Preparedness" on page 56 for specific inspection requirements.

Contact an authorized service agent immediately if:

- The unit is not functioning properly.
- Accessories show signs of deterioration.
- The unit was subjected to extreme mechanical stress.
- Status indicator displays a "Do Not Use" icon.

Service and Repair

WARNING Hazardous voltage. To reduce the risk of electrical shock, do not attempt to remove the cover under any circumstances. There are no operator serviceable components and only a qualified technician should service the Welch Allyn AED 10.

WARNING Do not disassemble the Welch Allyn AED 10. There are no operator serviceable components. Service and repair should be performed only by authorized service personnel.

If a Welch Allyn AED 10 needs servicing, contact a Welch Allyn authorized service agent (see page ii). Be prepared to provide the following information:

- Model
- Serial number
- Description of the problem
- Service log file

If the Welch Allyn AED 10 needs to be returned for servicing, use the original shipping container. If the shipping container is not available, contact Welch Allyn technical support for packing instructions prior to shipping. This will help minimize damage during shipping.

Note Information such as circuit diagrams, parts lists, descriptions, and calibration procedures needed to aid in repairing components designated as field repairable may be requested from Welch Allyn.

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Maintenance Schedule

Caution Improper maintenance may cause the Welch Allyn AED 10 to malfunction. Maintain the Welch Allyn AED 10 as described in this manual.

General

Prepare a customized maintenance schedule for the Welch Allyn AED 10 to reflect how the unit will be used. The schedule should account for how often the unit is used and where it is used. In addition, the schedule should consider how familiar the operators are with the operation of the unit. Here are some guidelines for preparing a maintenance schedule at your facility:

Frequency	Observe	Action
After each use and during each inspection	Check the status indicator. Verify that the "ready to use" status indicator on the front of the unit is operating.	If the status indicator is flashing, replace the battery. If a solid red symbol appears, turn on the AED 10, if possible, and note the self-test results. If a "Self-Test Failure" is indicated, remove AED 10 from service and contact Welch Allyn customer service. If the AED 10 will not power on, replace the battery as it is probably drained.
	Inspect exterior of Welch Allyn AED 10 and pad connector for any signs of damage.	Clean the Welch Allyn AED 10. If damaged, remove AED 10 from service and contact Welch Allyn customer service.
	Make sure that all supplies and accessories are present and in proper operating condition. Inspect the defibrillation pad packages, and battery packs for "install before dates" and any signs of damage.	Do not use damaged or expired supplies or accessories. Replace any used supplies and accessories such as razors, gloves, and pads.
After each use	Check battery	Check the battery capacity shown in the battery gauge on the display. If "Low Battery" is indicated, remove the battery and replace with a new battery. Dispose of the battery properly according to local authority disposal standards. Always verify that a fully charged spare battery is available for use.

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Checklists for Preparedness

Use *FDA Checklist and Automated External Defibrillators: Operator's Checklist* to help maintain the Welch Allyn AED 10 in an operation-ready condition.

An important part of a successful maintenance program is the creation of a maintenance log in which information is recorded on a regular basis. The log provides a:

- Record of the maintenance performed, who performed it, and when it was completed.
- Schedule of periodic requirements such as calibration and certification.
- Tracking of accessories, such as batteries, that require periodic testing and replacement.

Operator's Checklist

In accordance with the recommendations of the Defibrillator Working Group of the Food and Drug Administration (FDA), Welch Allyn has provided the following operator's checklist.

Automated External Defibrillator Operator's Checklist
Infrequent Use (Non-Rechargeable Battery)

Date: _____ Location:_____

Welch Allyn AED Serial No. or Facility ID No. _____

Description	OK as found	Corrective Action/Remarks
Defibrillator Unit		
Clean, no spills, clear of objects on top, casing intact		
Verify date and time		
Cables/Connectors		
Inspect for cracks, broken wire, or damage		
Connectors are engaged securely and are not damaged		
Supplies		
Two sets of pads in sealed packages within expiration date		
Hand towel		
Scissors		
Razor		
Alcohol wipes		
Spare battery		
Power Supply		
Verify non-rechargeable (long storage life) battery inserted and within the expiration date.		
Verify that the system ready indicator shows READY.		

_____ _____

Signature Print Name

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Cleaning and Disinfecting the Welch Allyn AED 10

Clean and disinfect the Welch Allyn AED 10 regularly and observe the following cleaning and disinfecting guidelines:

- Clean the unit with the battery in place to keep liquids out of the battery contact area. Make sure liquid does not get into the electrode pads connector.
- Use a soft cloth. Do not use abrasive materials, cleaners, or strong solvents such as acetone or acetone-based cleaners.

Caution Do not immerse any portion of the Welch Allyn AED 10 in water or other liquids. Avoid spilling any liquids on the Welch Allyn AED 10 or its accessories. Liquids may damage the unit or present a fire or shock hazard.

Caution Do not autoclave or gas sterilize the Welch Allyn AED 10 or accessories.

The following are recommended cleaning agents for use on the exterior of the Welch Allyn AED 10:

- Fantastik®
- Formula 409®
- Hydrogen peroxide solution
- INCIDIN®
- Liquid soap
- T.B.Q.®
- Warm water
- Wex-cide®
- Windex®

Never use any of the following cleaning agents on the Welch Allyn AED 10:

- Acetone
- Ammonia cleaner
- Benzene
- Butyl alcohol
- Denatured ethanol
- Enviroquat®
- Ether
- Freon
- Glutaraldehyde
- Isopropyl alcohol
- Chlorine bleach solution
- Misty®
- Staphene®
- Trichloroethane, trichloroethylene
- Vesphene II®

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Recycling Defibrillator Components

Within the European Union

Do not dispose of this product as "unsorted municipal waste". Prepare it for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE).

If the defibrillator or battery (LiMnO2) is contaminated, this directive does not apply.

For more specific information, see www.welchallyn.com/weee, or contact Welch Allyn Customer Service (page ii).

Recycle defibrillator batteries (LiMnO2) according to the Directive 91/157/EEC (Batteries and accumulators containing certain dangerous substances) and Directive 93/86/EEC (Labeling of batteries and accumulators containing certain dangerous substances).

Outside the European Union

When the defibrillator or the battery (LiMnO2) reaches end of life, recycle it locally according to national, state, and local regulations, or return it to Welch Allyn.

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6 Troubleshooting

This chapter provides information on how to troubleshoot situations and conditions that arise during the operation of the Welch Allyn AED 10 and gives answers to frequently asked questions.

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Overview

If the built-in sensors in the Welch Allyn AED 10 detect a problem prior to or during operation, the unit provides a voice or screen prompt indicating the problem.

Use the information in the following tables to troubleshoot. The tables list fault indicators and determine possible corrective actions.

Note In some situations, the operator will be instructed to change the battery or defibrillation electrode pads. It is important to always have spare batteries and other accessories available.

Attaching Electrode Pads

Indicator/Possible Cause	Corrective Action
Electrode pad does not adhere properly to the patient.	Wipe moisture from chest and/or shave excessive hair from chest.
Electrode pads are dry, damaged, or out-of-date.	Replace the electrode pads.
Improper pad placement or pads touching each other.	Check pad placement; make sure pads are in the correct location.
Inadequate connection to AED 10	Check for proper insertion of defibrillation pads connector into AED 10.
Pads connector not connected or properly inserted into the connector socket	Push pads connector firmly into the connector socket.
Poor defibrillation pad contact with the patient's bare chest.	Press firmly on electrode pads to improve adherence to patient's skin.

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Analyzing Interrupted

Indicator/Possible Cause	Corrective Action
Defibrillator pad removed.	Press electrode pad to firmly attach it to patient's skin. If needed, replace the pad.
Electrical interference or radio transmissions.	Remove possible sources of electrical or radio interference.
Electrical/radio frequency interference.	Move hand-held communication devices or other suspected devices away from the AED 10.
Electrode disconnected from patient or AED 10.	Check the connection to the AED 10.
Patient movement.	Move patient to stable location when possible.
Patient's motion (CPR, seizures, etc.)	Stop patient motion if possible.
Transportation of the patient during vehicle motion.	Stop patient movement or, if possible, stop vehicle transportation during analysis.

No Shock Delivered

Indicator/Possible Cause	Corrective Action
Electrode pad connector not properly connected to the Welch Allyn AED 10 socket.	Push pads connector firmly into Welch Allyn AED 10 connector socket.
Improper pad placement or pads touching each other.	Check pad placement. Use the pictures on the pads to make sure they are in correct location.
Pads, cable, or connector damaged.	Replace pads.
Poor defibrillation pad contact with patient's bare chest.	Press pads firmly to patient's bare chest.
	Wipe moisture from chest and/or shave excessive hair from chest.
	Replace the pad, if needed.
Shock button not pressed within fixed time limit.	Press Shock button within 30 seconds (Automated Mode) or 60 seconds (Manual Mode) after the ready message.
Electrode disconnected from patient or AED 10.	Check the connection to the AED 10.

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Defibrillator

Indicator/Possible Cause	Corrective Action
AED 10 operates, but LCD is too dark or too light.	Adjust the contrast setting.
AED 10 turns off or will not turn on.	Reinstall or replace the battery.
Battery depleted or disconnected.	Reinstall or replace the battery.
Displayed time or date is incorrect.	Change the AED 10 time setting. Verify that time is correct after a power ON/OFF cycle.
Electrical/radio frequency interference.	Move hand-held communication devices or other suspected devices away from the AED 10.
Operating temperature is too low or too high.	Operate the AED 10 between 0° to 50°C (32° to 122°F).

Battery

Indicator/Possible Cause	Corrective Action
AED 10 needs service.	Replace battery. If condition is not corrected, contact authorized service personnel.
Depleted battery. No display or messages after ON button is pushed.	Replace battery. If condition is not corrected, contact authorized service personnel. For battery recycling information, see "Recycling Defibrillator Components" on page 59.

Other Problems

Indicator/Possible Cause	Corrective Action
A fault requires service.	Continue to use the AED 10 if it is possible and needed. Contact authorized service personnel as soon as possible to repair the AED 10.
AED 10 operates, but LCD is blank. Operating temperature is too low or too high.	Operate the AED 10 between 0° and 50°C (32° and 122°F).
LCD not operating properly.	Contact authorized service personnel.
AED 10 always powers up with menu displayed.	Stuck lower menu button. Contact authorized service personnel.

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Frequently Asked Questions

Will the Welch Allyn AED 10 function correctly if I have reversed the placement of the electrode pads when I placed them on the patient's chest?

Yes. The Welch Allyn AED 10's ability to analyze the rhythm and to deliver shocks is independent of the polarity of the electrode pads. (See "Attach the Electrode Pads and Connect the Cable" on page 25.)

Do I select the energy level with successive shocks?

No. The energy level is preset when operating the Welch Allyn AED 10 in Automated Mode.

What do I do if a shock is advised while I am transporting a patient?

Avoid shocking a patient during transport; movement may interfere with the accuracy of the rhythm analysis. Stop the transport if possible and allow the Welch Allyn AED 10 to reconfirm the shockable condition.

What is the capacity of the battery?

Refer to "Battery Level Indicator" on page 16 for battery capacity specifications. When the unit is in storage, battery capacity will diminish over time. The Welch Allyn AED 10 continuously monitors and reports battery capacity while in storage. The battery level status indicator alerts you when the battery needs to be replaced.

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A Specifications

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Physical

Dimensions	8 1/4" x 6 7/8" x 2 3/4" (210 x 175 x 70 mm)
Weight	3.5 (1.6 kg) pounds with battery
Operating Temperature	32°F to 122°F (0°C to 50°C)
Storage Temperature (without battery)	-22°F to 158°F (-30°C to 70°C)
Humidity	Up to 95% (non-condensing)
Altitude	Up to 15,000 feet (-150 to 4570 m)
Shock	Mil Std 810E method 516.4, procedure 1 (30G, 6-9ms pulse, 1/2 sine each axis)
Vibration	Mil Std 810E method 514.4, category 1
Water resistance	IEC 60529 IPX4
Drop Test	Mil Std 810F method 516.5 Procedure IV (1 meter drop onto any edge, corner, or surface)

Electrical Isolation

Power	Unit operates on internal battery only
External Electrical Connections	No external devices are attached to the unit
Risk Current Category	Internally powered equipment with defibrillator-proof BF type patient applied part (as per definition of IEC 60601-1 standard)

Data Management

Event Documentation	Internal
Internal Memory Capacity	1MB: 250 4-sec ECG samples or 3000 time stamped events
Quick Report	Treatment Summary, Event Log, Test Log
Communication	RS-232 via Infrared (IR) port to PC or printer

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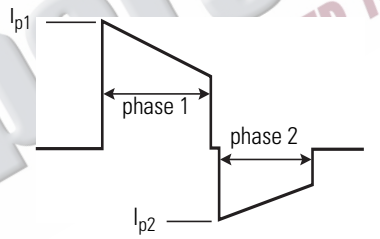
Defibrillator

Output	MRL Orbital™ Biphasic Truncated exponential
Energy Sequence (user configurable)	Shock 1: 150 J, 200 J Shock 2: 150 J, 200 J, 300 J Shock 3: 150 J, 200 J, 300 J, 360 J
Charge Time from "Shock Advised"	4 sec. to 150 J 8 sec. to 200 J 15 sec. to 360 J
Analysis Time	4-16 sec.
Combined Analysis and Charge Time	From start of analysis to shock ready:
from power up	Less than 20 seconds to 200 J
after 6 shocks	Less than 30 seconds to 360 J
Audible Prompts	18 audible prompts
Visual Prompts	20 text screen prompts
Controls	Four buttons - On/Off, Shock, and 2 software-configurable buttons
Waveform Details	The table below provides details of the biphasic truncated exponential waveform delivered by the AED 10 (set to Emax) when connected to resistive loads of 25 through 175 Ω. The waveforms are characterized by typical values for peak current (I_p), duration of the first output phase, and duration of the second output phase. Values are within 10%.



Patient Impedance (Ω)	I_{p1} (Amps)	I_{p2} (Amps)	t_{phase1} (ms)	t_{phase2} (ms)
25	52.2	35.7	5.6	3.8
50	26.5	16.9	11.6	7.7
75	17.5	11.8	16.6	9.9
100	13.3	9.3	18.8	9.9
125	10.5	7.7	19.9	10.3
150	8.9	6.8	20.2	10.3
175	7.5	6.0	20.4	10.3

Output Energy Accuracy	±10% or 1 J (whichever is greater) into 50 Ω impedance ±15% or 1 J (whichever is greater) into any impedance from 25 Ω to 125 Ω Typical transthoracic impedance with properly applied Welch Allyn defibrillation pads is under 125 Ω.

Pediatric Energy Reducer

Energy Attenuation Factor	25%, at 25 Ω, 50 Ω and 75 Ω
	20%, at 100 Ω and 125 Ω
	15%, at 150 Ω and 175 Ω

Display

Type	Backlit Monochrome LCD
Size	2.1" x 1.42" (54 x 36 mm)
Resolution	160 x 100
Freq Response	1 to 40 Hz
Low Battery Indicator	Battery Icon gauge on display with 10 capacity levels
Backlight	LED

Battery

Type	Non-rechargeable, LiMnO2 12V, 2.6 Ah
Capacity	90 discharges at 360 Joules or 125 discharges at 200 Joules or 150 discharges at 150 Joules or 5 hours ECG monitoring
Shelf Life 25°C ± 15°C	10 years (5 years storage + 5 years standby) 5 years standby (after installation)
	Battery capacity measured according to IEC 60601-1-2-4, claf use 102.3.2 at room temperature. Capacity may be diminished by extremes, or when the available battery charge is used in multiple power ON/OFF cycles.

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Electromagnetic Compatibility

Category	Standard	Level
Radiated Emissions	EN55011	CISPR11 B
ESD	EN61000-4-2	8kV air 6kV contact
Radiated Susceptibility	EN61000-4-3	10 V/m (20 V/m EN 60601-2-4)
Magnetic Field Emissions	MIL STD RE101	(AAMI DF2 4.3.18.1)
Magnetic Field Susceptibility	MIL STD RS101	1 Gauss, 47 Hz-1.8 kHz

Guidance and manufacturer's declaration—electromagnetic emissions (IEC 60601-1-2 Table 201)

The Welch Allyn AED 10 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED 10 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Welch Allyn AED 10 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CSPR 11	Class B	
Harmonic Emission IEC 6100-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

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Guidance and manufacturer's declaration—electromagnetic immunity (IEC 60601-1-2 Table 202)

The Welch Allyn AED 10 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED 10 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines	Not applicable	
	± 1 kV for input/ output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode	Not applicable	
	± 2 kV common mode	Not applicable	
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	Not applicable	
	40% U_T (60% dip in U_T) for 5 cycles	Not applicable	
	70% U_T (30% dip in U_T) for 25 cycles	Not applicable	
	<5% U_T (>95%dip in U_T) for 5 sec	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	10 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_T is the ac mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration—electromagnetic immunity (IEC 60601-1-2 Table 203)

The Welch Allyn AED 10 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED 10 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to any part of the Welch Allyn AED 10, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Conducted RF **IEC 61000-4-6**	3 V_{rms} 150 kHz to 80 MHz outside ISM bands[a]	3 V_{rms}	$d = 1.17 \sqrt{P}$
	10 V_{rms} 150 kHz to 80 MHz in ISM bands[a]	10 V_{rms}	$d = 1.20 \sqrt{P}$
Radiated RF **IEC 61000-4-3**	10 V/m 80 MHz to 2.5GHz	10 V/m	$d = 1.20 \sqrt{P}$ 80 to 800 MHz $d = 2.30 \sqrt{P}$ 800 MHz to 2.5 GHz

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[b]

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d]

Interference may occur in the vicinity of equipment marked with this symbol.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Welch Allyn AED 10 is used exceeds the applicable RF compliance level above, the Welch Allyn AED 10 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Welch Allyn AED 10.

d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V 1] V/m.

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Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn AED 10 (IEC 60601-1-2 Table 205)

The Welch Allyn AED 10 is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Welch Allyn AED 10 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn AED 10 as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)			
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz outside ISM bands**	**150 kHz to 80 MHz in ISM bands**	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = [3.5/3]^* \sqrt{P}$	$d = [12/10]^* \sqrt{P}$	$d = [12/10]^* \sqrt{P}$	$d = [23/10]^* \sqrt{P}$
0.01	0.17	0.12	0.12	0.23
0.1	0.37	0.38	038	0.73
1	1.17	1.20	1.20	2.3
10	3.69	3.79	3.79	7.27
100	11.70	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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Rhythm Recognition Performance

Standards

The Welch Allyn AED 10 algorithm exceeds the requirements of ANSI/AAMI DF39-1993 section 3.3.18 and the sensitivity and specificity levels recommended by the AHA *Automatic External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance*. The test database includes shockable rhythms consisting of ventricular fibrillation rhythms (> 99 υV) and wide-complex ventricular tachycardia at a rate greater than 160 BPM. Non-shockable rhythms include various sinus rhythms including supraventricular tachycardia, atrial fibrillation, atrial flutter, sinus rhythm with PVC's, asystole, pacemaker rhythms, and ventricular tachycardia with a rate less than 160 BPM and/or narrow complexes.

Performance

Rhythm Class	ECG Test Sample Size	Performance Goal	90% one-sided lower confidence level	Conclusion
Shockable: VF	90	>90% sensitivity	97.2%	Meets the AAMI DF39 requirement and AHA recommendation
Shockable: VT	33	>75% sensitivity	84.6%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: NSR	349	>99% specificity (AHA)	100%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: asystole	10	>95% specificity	100%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: all other rhythms	242	>95% specificity	97.8%	Meets the AAMI DF39 requirement and AHA recommendation

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Summary Of Studies Of Waveform Safety & Effectiveness

Introduction

Over 30 years ago, Medical Research Laboratories (MRL) patented a unique monophasic truncated exponential waveform, which utilized a low peak current, impedance compensated defibrillation waveform. The MRL monophasic waveform was developed as an alternative to the monophasic damped sine (MDS) waveform (often referred to as the Edmark waveform) defibrillator, which was associated with higher peak currents and did not actively compensate for varying patient impedances. In fact, the MRL monophasic waveform defibrillator delivers less than half of the peak current of an MDS waveform defibrillator at equal delivered energies. A new defibrillator (the Welch Allyn AED 10) has been introduced, which offers a biphasic truncated exponential waveform that incorporates MRL's original low peak current, impedance compensation design. The MRL Orbital™ biphasic truncated exponential waveform has been extensively tested in multiple scientific safety and effectiveness studies. Over 524 fibrillation/defibrillation shock episodes have been conducted using the MRL Orbital Biphasic waveform comparing it to MDS, MTS and another commercially available 2kV biphasic (360 J capable) defibrillators. Results of three of the scientific safety and effectiveness studies are summarized below.

Study 1

Objective

To evaluate the MRL Orbital Biphasic waveform defibrillator against a monophasic damped sinusoidal waveform defibrillator.

Methods

A canine model (n=5, 71±7 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with 20 mpk sodium pentothal i.v., and maintained as required through an intravenous catheter in the foreleg. The external jugular vein was cannulated and a bipolar pacing catheter was introduced under fluoroscopic control and advanced into the right ventricle. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure. The chest was shaved and defibrillating patch electrodes (R2 part number 3200-1715) were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the right ventricular electrode. The energy required to defibrillate was determined by a protocol that has been used in several other biphasic comparison studies. An initial shock strength of 50 to 70 joules was used. If successful, VF is reinduced after a 4-minute rest period, and the shock strength is reduced by approximately 20% for the next defibrillation attempt. If the initial shock fails, a rescue shock is delivered, and after a rest period, VF is again induced. The energy is now increased about 20% for the next defibrillation attempt. This procedure was continued until at least 3 reversals in result were observed with each waveform. Two ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. In practice, actual clinical units were used, so the energy steps were limited to those selectable on the devices tested.

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Results

The study consisted of 82 total fibrillation/defibrillation episodes. ID50 peak currents and ED50 delivered energies are shown below for each group. The mean impedance for these animals was 62 Ω. The mean ED50 energies were compared and were found to be significantly different. The significance of difference (p-value) was calculated by the Wald test in each case, and is shown below. The mean ED50 peak current for the biphasic waveform was 39 percent of that required with the MDS waveform.

Summary Table - ED50 & ID50

Mean	Welch Allyn AED 10	Monophasic Damped Sine
ID50 Peak Current (Amps)	6.4	16.6
Significance of difference (p-value)	<0.001	
ED50 Delivered Energy (Joules)	26.3	35.3
Significance of difference (p-value)	0.014	

Conclusion

The MRL Orbital Biphasic waveform is capable of converting fibrillation episodes using less energy than the MDS waveform, and requires lower peak currents than MDS waveform defibrillators.

Study 2

Objective

Comparison of the defibrillation effectiveness of the MRL Orbital Biphasic waveform defibrillator, with a commercially available Biphasic 2kV defibrillator capable of 360 J and a monophasic truncated exponential defibrillator.

Methods

A canine model (n=6, 61.6 ± 5.5 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with an intravenous injection of 20 mg/kg sodium pentothal. They were then intubated with a cuffed endotracheal tube, and maintained on isoflurane gaseous anesthetic. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure, and for acquiring samples for arterial blood gas and electrolyte monitoring. The chest was shaved and adhesive defibrillating electrode pads were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the external electrodes. The ED50 energy (that required to defibrillate with 50% probability) was determined by a protocol modeled after that of Dixon. An initial shock strength of 30 joules was used, which was applied after 15 seconds of ventricular fibrillation (VF). If successful, VF was re-induced after a 4-minute rest period, and the shock strength was reduced by one energy step for the next defibrillation attempt. If the initial shock failed, a rescue shock was delivered, and after a rest period, VF was again induced. The energy was now increased one energy step for the next defibrillation attempt. This procedure was continued until a nominal sample size of six episodes was achieved (both sides of the first reversal in result, plus 4

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episodes). Three ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. After each of the three independent ED50 estimation procedures had been completed, the entire protocol was repeated twice more, each time starting all devices at an energy of 30 joules. The ED50 peak current and energy was then estimated for each animal by logistic regression analysis. Individual phase durations and overall pulse durations were measured and recorded on each shock.

Results

The study consisted of 344 total fibrillation/defibrillation episodes. The mean ED50 and ID50 estimates (to one decimal place) are shown below. The significance of difference (p-value) was calculated by the Wald test in each case, and is shown below. Also shown are the mean total durations measured for each device.

Summary Table -ED50, ID50, & Duration

Mean	Monophasic Waveform	Welch Allyn AED 10	2kV Biphasic Waveform
ID50 Peak Current (Amps)	9.0	6.4	8.3
Significance of difference (p-value)	<0.001 (Welch Allyn AED 10 vs. Monophasic)		<0.001 (Welch Allyn AED 10 vs. 2kV Biphasic)
ED50 Delivered Energy (Joules)	40.2	21.4	22.7
Significance of difference (p-value)	<0.001 (Welch Allyn AED 10 vs. Monophasic)		<0.4937 (Welch Allyn AED 10 vs. 2kV Biphasic)
Total Duration (msec)	11.9	12.3	13.1

Conclusion

The MRL Orbital Biphasic waveform was as effective as the Biphasic 2kV waveform, and more effective than the monophasic waveform. While both biphasic waveforms required less peak current than the monophasic waveform, the MRL Orbital Biphasic waveform required statistically less peak current than the 2 kV biphasic waveform defibrillator.

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Study 3

Objective

Comparison of the defibrillation effectiveness of the MRL Orbital Biphasic waveform defibrillator, with a commercially available Biphasic 2kV defibrillator capable of 360 J in a simulated higher impedance model.

Methods

A canine model (n=6, 53.7 ± 6.1 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with 20 mpk sodium pentothal i.v., and maintained as required through an intravenous catheter in the foreleg. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure. The chest was shaved and defibrillating patch electrodes were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the chest electrodes. The energy required to defibrillate was determined by a protocol that has been used in several other biphasic comparison studies. An initial shock strength of 70 to 100 joules was used. If successful, VF was re-induced after a 5 minute rest period, and the shock strength was reduced by approximately 20% for the next defibrillation attempt. If the initial shock failed, a rescue shock was delivered, and after a rest period, VF was again induced. The energy was now increased about 20% for the next defibrillation attempt. This procedure was continued until approximately 4 reversals in result were observed with each waveform. Two ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. In practice, actual clinical units were used, so the energy steps were limited to those selectable on the devices tested. The ED50 peak current and energy was then estimated for each animal by logistic regression analysis.

This study simulated a higher impedance patient by having a 32-Ω resistor placed in series with each subject.

Results

The study consisted of 98 total fibrillation/defibrillation episodes. The mean ED50 and ID 50 estimates for peak current and energy for each animal (to one decimal place) are shown below. The significance of difference (p-value) was calculated by the Wald test in each case, and is shown below. Also shown are the mean total durations measured for each device.

Summary Table -ED50, ID50, & Duration

Mean	**Welch Allyn AED 10**	**2kV Biphasic Waveform**
ID50 Peak Current (Amps)	5.8	7.4
Significance of difference (p-value)	<0.001	
ED50 Delivered Energy (Joules)	34.3	32.0
Significance of difference (p-value)	0.885	
Total Duration (msec)	21.3	15.6

Conclusion

The MRL Orbital Biphasic waveform was as effective as the 2kV Biphasic waveform in this model of a higher impedance patient. When these devices are compared on the basis of peak current, the MRL Orbital Biphasic required less peak current than the 2kV Biphasic waveform.

Rationale for Animal Studies

Electrical waveforms for transthoracic ventricular defibrillation have been well studied for nearly 50 years. These studies led to the development of monophasic waveforms such as the Edmark, Lown, and truncated exponential waveforms that have now been used in humans for over 30 years. Starting in the early 1980s, biphasic waveforms have been extensively studied in animal models of transthoracic ventricular defibrillation. These studies have shown that a wide variety of biphasic waveforms exhibited superior defibrillation effectiveness to these conventional monophasic waveforms. In many cases, the waveform comparisons performed in animals were repeated in clinical trials involving humans. These studies have conclusively demonstrated that well-designed animal studies can and do predict the results that will be observed in humans.

The reasons for conducting animal trials (as opposed to additional human clinical studies) are:

1. Animal studies can use a much larger sample size (more shocks per subject), and thus, result in far more accurate comparisons.
2. Animal studies do not place human subjects at risk from additional (and clinically unneeded) shocks.
3. The animal hearts can be inspected for damage after the defibrillation studies.

Waveform Safety & Effectiveness Conclusions:

These scientific studies have demonstrated that:

- The data suggests that the MRL Orbital Biphasic waveform in the Welch Allyn AED 10 is at least as effective as, and may be more effective than either of the two tested monophasic waveforms, appearing to allow termination of fibrillation episodes using lower energies.
- The MRL Orbital Biphasic waveform in the Welch Allyn AED 10 is as effective as the 2kV biphasic truncated exponential waveform in another commercially available defibrillator.
- The MRL Orbital Biphasic waveform in the Welch Allyn AED 10 requires less peak current to achieve defibrillation effectiveness than either of the two monophasic waveforms or the 2kV biphasic truncated exponential waveform that is used in another commercially available defibrillator.

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B Glossary

AED automated external defibrillator

AHA American Heart Association

ALS advanced life support

arrhythmia irregular rhythm of the heart muscle

BLS basic life support

bradycardia abnormally slow heart rate

cardiac arrest cessation of the heart muscle

CPR cardiopulmonary resuscitation

defibrillation high-energy pulse of electricity (shock) delivered to the heart muscle to restore normal cardiac activity

defibrillation protocol preset order and level of the shock energy delivered at defibrillation (for example 200, 200, 360 Joules or 200, 300, 360 Joules)

ECG electrocardiogram

electrocardiogram curve traced by an electrocardiograph

electrocardiograph instrument used to record electrical currents associated with heart muscle activity

EMS emergency medical services

erythema redness of the skin

fibrillation rapid twitching movements that replace the normal rhythmic contraction of the heart and may cause a lack of circulation and pulse

joule the amount of energy delivered during defibrillation, related to the intensity of the shock delivered

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LCD liquid crystal display (AED 10 screen)

log list of ECG samples and time-stamped system events

nonshockable rhythm patient heart rhythms that are not a candidate for defibrillation pulse

NSR normal sinus rhythm

Primary AED AED 10 mode that provides text and voice prompts

protocol *see* defibrillation protocol

RF radio frequency

SCA sudden cardiac arrest

self-test automatic test performed at system power-up to check readiness of battery, internal circuitry, main processor, and defibrillator

shock defibrillation electrical pulse

shockable rhythm abnormal heart rhythm which is a candidate for defibrillation pulse

tachycardia an abnormally fast heart rate

time-stamped event any change in heart rhythm or any shock delivered by the defibrillator

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